UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, LLC, Plaintiffs, v. EAGLE PHARMACEUTICALS INC. Defendant.	Case No. 18-cv-823-CFC-JLH [redacted]

DECLARATION OF JOHN C. JAROSZ
DECEMBER 16, 2021

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I. INTRODUCTION

A. Assignment

1. I have been retained by Par Pharmaceutical, Inc. ("Par Pharmaceutical"), Par Sterile Products, LLC ("Par Sterile Products"), and Endo Par Innovation Company, LLC ("EPIC") (collectively, "Plaintiffs") in their patent infringement lawsuit against Eagle Pharmaceuticals, Inc. ("Eagle" or "Defendant").[1]

2. Plaintiffs have accused Eagle of infringing Par Pharmaceutical's U.S. Patent Nos. 9,744,209 ("the '209 Patent") and 9,750,785 ("the '785 Patent") (collectively, the "Patents at Issue").[2]

3. I understand that the Patents at Issue are embodied in Plaintiffs' Vasostrict® (vasopressin) products.[3]

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1 "Complaint," 1:18-cv-00823, May 31, 2018 ("Complaint v. Eagle").

2 Complaint v. Eagle; "Memorandum Opinion," Chief Judge Colm F. Connolly of the U.S. District Court for the District of Delaware, August 31, 2021 ("Non-Infringement Opinion, August 31, 2021"); "Final Judgment," Chief Judge Colm F. Connolly of the U.S. District Court for the District of Delaware, September 14, 2021 ("Non-Infringement Final Judgment, September 14, 2021"), at ¶¶ 1-2. Plaintiffs initially asserted four additional patents against Eagle. *See* Complaint v. Eagle, at ¶ 5. The claims and counterclaims asserted relating to those patents were dismissed later during the course of this lawsuit. *See* Non-Infringement Final Judgment, September 14, 2021, at ¶ 3.

3 Endo International PLC SEC Form 10-K for the fiscal year ended December 31, 2018 ("Endo 2018 10-K"), at p. 9. *See also*, "Declaration of Mark Bradley in Support of Plaintiffs' Motion for a Preliminary Injunction Pending Appeal," 1:18-cv-00823, December 16, 2021 ("Bradley Declaration"), at ¶¶ 7-9.

4. Eagle has submitted an Abbreviated New Drug Application ("ANDA") No. 211538 (the "Eagle ANDA") to the U.S. Food and Drug Administration ("FDA") "seeking approval to engage in the commercial manufacture, use, and sale of a proposed generic Vasopressin Injection USP, 20 units/1 mL (20 units/mL)" product ("Eagle Generic" or "Generic").[4] Plaintiffs claim that Eagle's Generic infringes the Patents at Issue.[5]

5. On August 31, 2021, Chief Judge Colm F. Connolly of the U.S. District Court for the District of Delaware found that "Eagle does not infringe claims 1, 4, 5, and 7 of [the '209 Patent] and claims 1, 5, and 8 of [the '785 Patent]."[6]

6. I understand that Plaintiffs have appealed Chief Judge Connolly's non-infringement decision.

7. I have been asked to provide expert economic analysis and testimony, if necessary, related to Plaintiffs' motion for a preliminary injunction prohibiting the U.S. manufacture, offer for sale, and sale of Eagle's Generic until the resolution of Plaintiffs' appeal of Chief Judge Connolly's finding of non-infringement.

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4 Complaint v. Eagle, at p. 7. I refer to Eagle Pharmaceuticals' pending generic Vasostrict® products as Eagle Pharmaceuticals' "Generic" products.

5 Complaint v. Eagle, at pp. 2, 16-18.

6 Non-Infringement Opinion, August 31, 2021.

8. This declaration summarizes the opinions that I have formed to date. I may modify or supplement my opinions, if necessary and allowed, based on review and analysis of information provided to me after the filing of this declaration.

B. Qualifications

9. I am a Managing Principal of Analysis Group, Inc. ("AG") and Director of the firm's Washington, DC office. AG is an economic, financial, strategy, and health care consulting firm with offices in Beijing, China; Boston, MA; Brussels, Belgium; Chicago, IL; Dallas, TX; Denver, CO; London, UK; Los Angeles, CA; Menlo Park, CA; Montreal, Quebec; New York, NY; Paris, France; San Francisco, CA; and Washington, DC. AG provides research and analysis in a variety of business, litigation, and regulatory settings.

10. I received my B.A. in Economics and Organizational Communications, *summa cum laude*, from Creighton University in Omaha, NE. Thereafter, I was a fellowship student in the Ph.D. program in Economics at Washington University in St. Louis, MO. I completed most of the degree requirements but left before finishing my Ph.D. degree. I ultimately was awarded an M.A. in Economics. I worked for some period after that and then enrolled in law school at the University of Wisconsin in Madison, WI. From there, I received a J.D., concentrating on courses covering the intersection of law and

economics. I am a member of the State Bar of Wisconsin but have been on inactive status for the past 36 years.

11. My resume, which describes all my testimony, publications, and presentations, is attached as Tab 1. To briefly summarize, I have spent my entire professional career as a practicing economist. Almost all my work has involved evaluating the economics of intellectual property ("IP") protection. The bulk of that work has dealt with issues of damages estimation; commercial success; fair, reasonable, and non-discriminatory ("FRAND") compliance; injunctive relief; and antitrust violations. I have testified at trial or arbitration in over 100 such matters.

12. Among other things, I have published articles in academic and professional journals, edited a treatise on IP licensing, given presentations and speeches to a wide variety of groups, and taught classes at various graduate schools.

13. Though our firm and I have been engaged in a wide range of industries, the largest amount of my work has been in pharmaceutical settings, where I have been involved in scores of matters. Those matters often deal with patient, physician, and payer decision-making, as well as supplier actions and reactions to competitive conditions.

C. Evidence Considered

14. In preparing this declaration, I have considered information from a variety of sources, each of which is a type that is reasonably relied upon by experts in my field. The documents that I considered are identified in Tab 2. In addition, I and people working under my direction and supervision have spoken with several people from Plaintiffs, Endo International PLC ("Endo," Plaintiffs' parent company), and other Endo subsidiaries:[7]

- Mark Bradley, Executive Vice President and Chief Financial Officer of Endo;[8]
- Guy Donatiello, Senior Vice President for Intellectual Property of Endo Pharmaceuticals, Inc.;[9]
- Larry Brown, Vice President for Intellectual Property and Assistant General Counsel of Par Pharmaceutical;[10] and

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7 Endo International PLC SEC Form 10-K for the fiscal year ended December 31, 2019 ("Endo 2019 10-K"), at Exhibit 21.1.

8 Bradley Declaration, at ¶¶ 1-2.

9 "Guy Donatiello," LinkedIn, https://www.linkedin.com/in/guy-donatiello-b278252/ (viewed December 5, 2021).

10 "Lawrence Brown," LinkedIn, https://www.linkedin.com/in/lawrence-brown-3aa6329/ (viewed December 7, 2021).

- Rich Valiga, Vice President for Financial Planning and Analysis of Endo Pharmaceuticals, Inc.[11]

15. I also have relied upon my professional judgment and expertise, gathered in many years of evaluating and valuing intellectual property rights.

D. Compensation

16. My firm has billed Plaintiffs on a time-and-materials basis for my work and that of my colleagues. My hourly billing rate for the time spent consulting, which includes my study of pertinent issues and materials, and any testimony I may give, is $870. I also have directed the efforts of other Analysis Group consultants, whose hourly billing rates range from $250 to $565. My compensation is not, in any way, dependent on the outcome of this proceeding or on the substance of my opinion.

E. Summary of Conclusions

17. Based upon review and analysis of the evidence that I have received to date, it is my opinion that Plaintiffs are likely to be irreparably harmed if there were to be an at-risk launch of the Eagle Generic. The FDA approved the Eagle Generic yesterday and, I understand, Eagle has represented that it intends to

[11] "Rich Valiga," LinkedIn, https://www.linkedin.com/in/rich-valiga-a564846/ (viewed December 5, 2021).

launch at-risk.[12] If Eagle actually launches at-risk, it would be exceedingly difficult to calculate all of the harm to Plaintiffs resulting from that launch with reasonable certainty and grant an adequate damages award after a later damages trial covering the full extent of the impact that Plaintiffs would suffer as a result of the generic launch.

18. Furthermore, it is my opinion that the balance of hardships in this matter weighs in favor of Plaintiffs. The likely harm here will severely threaten Plaintiffs' business and, perhaps, their corporate viability. On the other hand, postponing the launch of this potential business line until after the appeal is resolved would have limited financial and strategic impact on Eagle, particularly considering that it has not yet been in the business, as Plaintiffs have for many years.

19. Finally, it is my opinion that the public interest would, on balance, be served through a finding in favor of Plaintiffs and the issuance of the requested preliminary injunction. Not only would such a finding confirm the merits of a strong patent protection system and the innovation incentives it creates, but it would not disrupt (and likely would ensure) the uninterrupted supply of

12 "Eagle Pharmaceuticals Announces FDA Maintains Prioritization of ANDA for Vasopressin," Eagle, https://investor.eagleus.com/press-releases/news-details/2021/Eagle-Pharmaceuticals-Announces-FDA-Maintains-Prioritization-of-ANDA-for-Vasopressin/default.aspx (viewed December 4, 2021).

vasopressin to patients who may suffer from life-threatening health emergencies.

II. BACKGROUND

A. Parties

1. Plaintiffs

20. Plaintiffs Par Pharmaceutical, Par Sterile Products, and EPIC are wholly-owned subsidiaries of Endo.[13] Endo is a "specialty branded and generics pharmaceutical company."[14] It has four business segments: 1) "Branded Pharmaceutical," 2) "Sterile Injectables," 3) "Generic Pharmaceuticals," and 4) "International Pharmaceuticals."[15] Across those four segments, Endo generated total revenues of approximately $2.9 billion in 2020.[16] As of February 2021, Endo had approximately 3,400 employees.[17]

21. Founded in New York in 1978, Par Pharmaceutical is a company that "specializes in modified-released oral solid dosage forms as well as non-oral

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13 Endo 2019 10-K, at Exhibit 21.1.

14 Endo 2019 10-K, at p. 1.

15 Endo 2019 10-K, at p. 1.

16 Endo International PLC SEC Form 10-K for the fiscal year ended December 31, 2020 ("Endo 2020 10-K"), at p. 1.

17 Endo 2020 10-K, at p. 15.

dosage forms, […] and other alternative drug delivery platforms."[18] Par Pharmaceutical was listed on the American Stock Exchange after an initial public offering in 1984.[19] Par Pharmaceutical was subsequently listed on the New York Stock Exchange in 1987.[20] In 2005, Par Pharmaceutical received approval from the FDA to launch "its first branded product, Megace® ES*."[21]

22. In 2014, Par Pharmaceutical announced that it had received approval for its New Drug Application ("NDA") for Vasostrict® ("Vasostrict"), the first vasopressin injection product to be approved.[22]

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18 "Par Pharmaceutical Companies, Inc. History," Funding Universe, http://www.fundinguniverse.com/company-histories/par-pharmaceutical-companies-inc-history/#:~:text=Par%20Pharmaceutical%20was%20incorporated%20in,the%20company's%20chief%20executive%20officer (viewed December 2, 2020); "An Endo International Company," Par Pharmaceutical, https://www.parsterileproducts.com/ (viewed December 2, 2020).

19 "Par Pharmaceutical Companies Our History," Par Pharmaceutical, https://web.archive.org/web/20150321031532/http://www.parpharm.com/index.php?option=com_content&view=article&id=75&Itemid=92 (viewed December 2, 2020).

20 "Par Pharmaceutical Companies Our History," Par Pharmaceutical, https://web.archive.org/web/20150321031532/http://www.parpharm.com/index.php?option=com_content&view=article&id=75&Itemid=92 (viewed December 2, 2020).

21 "Par Pharmaceutical Companies Our History," Par Pharmaceutical, https://web.archive.org/web/20150321031532/http://www.parpharm.com/index.php?option=com_content&view=article&id=75&Itemid=92 (viewed December 2, 2020).

22 "Par Pharmaceutical Announces First FDA Approval of Vasostrict™ (vasopressin injection, USP)," PR Newswire, https://www.prnewswire.com/news-releases/par-pharmaceutical-announces-first-fda-approval-of-vasostrict-vasopressin-injection-usp-282391581.html#:~:text=Par%20Pharmaceutical%20Companies%2C%20Inc.&text=today%20announced%20that%20it%20has,%2C%20Drug%2C%20and%20Cosmetic%20Act. (viewed December 2, 2020); Endo 2019 10-K, at p. 4.

23. In May 2015, it was announced that Par Pharmaceutical would be acquired by Endo, as part of Endo's acquisition of Par Pharmaceutical Holdings, Inc. ("Par Holdings," Par Pharmaceutical's parent company at that time).[23] Par Pharmaceutical operates as a subsidiary of Endo and has approximately 400 employees.[24] [redacted][25] Through the first nine months of 2021, Vasostrict's over [redacted] million net revenues represent [redacted] percent of Endo's total revenues.[26]

24. Par Sterile Products was formerly JHP Pharmaceuticals, LLC ("JHP").[27] In January 2014, Par Pharmaceutical acquired JHP.[28] At that time, JHP was "a

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23 "Endo to Acquire Par Pharmaceutical, Strategically Expanding Generics Business to a Top 5 Industry Leader," Endo, https://investor.endo.com/news-releases/news-release-details/endo-acquire-par-pharmaceutical-strategically-expanding-generics (viewed December 2, 2020); Par Pharmaceutical Holdings, Inc., SEC Form S-1, March 12, 2015 ("Par Holdings March 12, 2015 S-1"), at p. 1.

24 "Par Pharmaceutical, Inc.," Dun & Bradstreet, https://www.dnb.com/business-directory/company-profiles.par_pharmaceutical_inc.a5e909cadd10c29d3f33a26e357e3095.html (viewed December 2, 2020); Endo 2019 10-K, at Exhibit 21.1.

25 [redacted] Tab 4, Tab 6, Tab 7.

26 Calculated as [redacted]

See Endo International PLC SEC Form 10-Q for the quarterly period ended September 30, 2021 ("Endo 3Q 2021 10-Q"), at p. 12.

27 Par Holdings March 12, 2015 S-1, at p. 1.

28 "Par Pharmaceutical to Acquire JHP Pharmaceuticals," PR Newswire, https://www.prnewswire.com/news-releases/par-pharmaceutical-to-acquire-jhp-

leading specialty pharmaceutical company that develops, manufactures and markets branded and generic sterile injectable products."[29] Before being acquired by Par Sterile Products, JHP "manufacture[d] and [sold] branded and generic aseptic injectable pharmaceuticals in hospital and clinical settings," and "provide[d] contract manufacturing services for global pharmaceutical companies."[30]

25. Par Pharmaceutical operated the acquired JHP business under the name "Par Sterile Products," which continued to "develop[], manufacture[] and market[] both branded and generic aseptic injectable pharmaceuticals."[31] Par Sterile Products was acquired by Endo in 2015, as part of Endo's acquisition of Par

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pharmaceuticals-241264801.html (viewed December 2, 2020); "Par Pharmaceutical Companies, Inc. History," Funding Universe, http://www.fundinguniverse.com/company-histories/par-pharmaceutical-companies-inc-history/#:~:text=Par%20Pharmaceutical%20was%20incorporated%20in,the%20company's%20chief%20executive%20officer (viewed December 2, 2020).

29 "Par Pharmaceutical to Acquire JHP Pharmaceuticals," PR Newswire, https://www.prnewswire.com/news-releases/par-pharmaceutical-to-acquire-jhp-pharmaceuticals-241264801.html (viewed December 2, 2020).

30 "Par Pharmaceutical to Acquire JHP Pharmaceuticals," PR Newswire, https://www.prnewswire.com/news-releases/par-pharmaceutical-to-acquire-jhp-pharmaceuticals-241264801.html (viewed December 2, 2020).

31 "Par Pharmaceutical Companies Our History," Par Pharmaceutical, https://web.archive.org/web/20150321031532/http://www.parpharm.com/index.php?option=com_content&view=article&id=75&Itemid=92 (viewed December 2, 2020).

Holdings, the parent company of Par Sterile Products.[32] Par Sterile Products operates as a subsidiary of Endo and has approximately 350 employees.[33]

26. For each of the five years from 2016 through 2020, Endo's long-term debt exceeded $8 billion.[34] Endo's debt was approximately $8.3 billion in 2020,[35] and has continued to exceed $8 billion through September 2021.[36]

2. Defendant

27. Defendant Eagle develops innovations associated with FDA-approved, injectable drugs that are said to offer advantages over readily-available alternatives.[37] Eagle develops and commercializes injectable drugs that focus primarily on the Central Nervous System critical care and oncology.[38]

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32 "Endo to Acquire Par Pharmaceutical, Strategically Expanding Generics Business to a Top 5 Industry Leader," Endo, https://investor.endo.com/news-releases/news-release-details/endo-acquire-par-pharmaceutical-strategically-expanding-generics (viewed December 2, 2020); Par Holdings March 12, 2015 S-1, at p. 1.

33 Endo 2019 10-K, at Exhibit 21.1; "Par Sterile Products, LLC," Dun & Bradstreet, https://www.dnb.com/business-directory/company-profiles.par_sterile_products_llc.f8a2e095a2de2ce409ca583abf87cb9a.html (viewed December 2, 2020).

34 Tab 5.

35 Tab 5. As of 2020, Endo's total assets amounted to approximately $9.3 billion.

36 Endo 3Q 2021 10-Q, at p. 1.

37 Eagle Pharmaceuticals, Inc. SEC Form 10-K for the fiscal year ended December 31, 2020 ("Eagle 2020 10-K"), at p. 9.

38 Eagle Pharmaceuticals, Inc. SEC Form 10-K for the fiscal year ended December 31, 2019 ("Eagle 2019 10-K"), at p. 4.

28. Incorporated in 2007, Eagle is headquartered in Woodcliff Lake, New Jersey.[39] As of the end of 2020, Eagle had 106 employees in the U.S.[40] In 2020, Eagle generated total revenues of approximately $190 million, with over $70 million generated by product sales, approximately $110 million generated by royalty revenue, and approximately $5 million generated by licenses and other revenue.[41] As of the end of 2020, Eagle had marketed three FDA-approved drugs, Ryanodex®, Belrapzo®, and Bendeka®.[42] Eagle partners with Teva Pharmaceutical Industries Ltd. to market Bendeka®.[43]

B. Patents at Issue

29. As noted above, Eagle has submitted the Eagle ANDA (No. 211538) "seeking approval to engage in the commercial manufacture, use, and sale of a proposed generic Vasopressin Injection USP, 20 units/1 mL (20 units/mL)."[44] The Eagle ANDA references Plaintiffs' Vasostrict "as the reference listed drug."[45]

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39 Eagle 2019 10-K, at p. 26.

40 Eagle 2020 10-K, at p. 28.

41 Eagle 2020 10-K, at p. 69.

42 Eagle 2020 10-K, at p. 31.

43 Eagle 2019 10-K, at p. 4.

44 Complaint v. Eagle, at p. 7.

45 Complaint v. Eagle, at p. 7.

30. Plaintiffs claim that Eagle's Generic infringes Par Pharmaceutical's U.S. Patent Nos. 9,744,209 and 9,750,785.[46] Eagle has denied that Eagle's Generic infringes those patents.[47] Eagle also has claimed that the Patents at Issue are invalid and unenforceable.[48]

1. The '209 Patent

31. The '209 Patent, titled "Vasopressin Formulations for Use in Treatment of Hypotension," was issued to Par Pharmaceutical on August 29, 2017.[49] The patent explains that "[v]asopressin can be used clinically in the treatment of sepsis and cardiac conditions, and in the elevation of patient's [sic] suffering from low blood pressure," but that "[then] [c]urrent formulations of vasopressin suffer from poor long-term stability."[50] The claims of the '209 patent recite methods of increasing blood pressure in humans, which comprise administering to the patient compositions of vasopressin with specified ranges of pH and impurities.[51]

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46 Complaint v. Eagle, at pp. 2, 16-18.

47 "Answers to Complaint & Counterclaims," 1:18-cv-00823, August 6, 2018 ("Eagle Answers"), at pp. 16-18.

48 Eagle Answers, at pp. 29-31, 34-36.

49 U.S. Patent No. 9,744,209, at p. 1.

50 U.S. Patent No. 9,744,209, at PDF p. 25.

51 U.S. Patent No. 9,744,209, at PDF pp. 82-83.

2. The '785 Patent

32. The '785 Patent, titled "Vasopressin Formulations for Use in Treatment of Hypotension," was issued to Par Pharmaceutical on September 5, 2017.[52] The patent explains that "[v]asopressin can be used clinically in the treatment of sepsis and cardiac conditions, and in the elevation of patient's [sic] suffering from low blood pressure," but that "[then] [c]urrent formulations of vasopressin suffer from poor long-term stability."[53] The claims of the '785 patent recite compositions of vasopressin with specified ranges of pH and impurities.[54]

C. Products at Issue

1. Vasostrict

33. The use of vasopressin products dates back to the early 20th century.[55] For many years, vasopressin has been used in injectable form as a treatment for various types of shock and cardiac arrest.[56]

34. From 2006 through 2011, the FDA launched the "Unapproved Drugs Initiative" ("UDI"), with the goal of "taking steps to […] encourage the

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52 U.S. Patent No. 9,750,785, at p. 1.

53 U.S. Patent No. 9,750,785, at PDF p. 25.

54 U.S. Patent No. 9,750,785, at PDF pp. 81-82.

55 Trial Exhibit DTX-25 (Pre NDA Meeting Package), at DTX025.009-10.

56 Trial Exhibit DTX-25 (Pre NDA Meeting Package), at DTX025.009-10.

manufacturers of [previously unapproved drugs] to obtain the required evidence and comply with approval provisions […].”[57]

35. In September 2012, Par Sterile Products submitted NDA No. 204485 to the FDA for marketing approval of Vasostrict.[58] In April 2014, Par Sterile Products received FDA approval for Vasostrict.[59]

36. The product, whose active ingredient is vasopressin, is administered through an intravenous (“IV”) injection.[60] I understand that vasopressin “is a nonapeptide synthesized in the hypothalamus.”[61] I understand that medical studies suggest that vasopressin can be used to treat “cardiopulmonary resuscitation (CPR), septic shock, intraoperative hypotension, and portal

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57 FDA, “Guidance of Marketed Unapproved Drugs; Compliance Policy Guide; Availability,” *Federal Register*, Vol. 71, No. 111 (June 9, 2006); FDA, “Marketed Unapproved Drugs — Compliance Policy Guide Sec. 440.100, Marketed New Drugs Without Approved NDAs or ANDAs,” (September 19, 2011).

58 “NDA 204485,” Department of Health and Human Services, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/204485Orig1s000ltr.pdf.

59 “Prescribing Information,” FDA, https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/204485Orig1s000lbl.pdf; “Approval Package for: Application Number: 204485Orig1s003,” Center for Drug Evaluation and Research, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/2044850Orig1s003.pdf.

60 “Prescribing Information,” FDA, https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/204485Orig1s000lbl.pdf; “Approval Package for: Application Number: 204485Orig1s003,” Center for Drug Evaluation and Research, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/2044850Orig1s003.pdf.

61 Treschan, Tanja, and Jurgen Peters, “The Vasopressin System,” *Anesthesiology,* Vol. 105, No. 3 (2006): 599-612 (“Treschan et al (2006)”), at p. 599.

venous hypertension."[62] Vasostrict is indicated to increase blood pressure in adults who remain hypotensive after receiving fluids and catecholamines after vasodilatory shock.[63]

37. In June 2016, Endo announced that Par Pharmaceutical, which Endo owned, had received patent protection for Vasostrict with the issuance of U.S. Patent No. 9,375,478 Patent (the "'478 Patent") by the U.S. Patent and Trademark Office ("PTO").[64] The '478 Patent was submitted to the FDA "Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, [with] a submission date of June 28, 2016."[65] According to Endo, Par Pharmaceutical's Vasostrict patents, which now include the Patents at Issue, will remain effective through January 30, 2035.[66]

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62 I understand that vasopressin "have been used traditionally to treat upper gastrointestinal bleeding, central diabetes insipidus, and bleeding disorders." Treschan et al (2006), at p. 599.

63 "Prescribing Information," FDA, https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/204485Orig1s000lbl.pdf; "Approval Package for: Application Number: 204485Orig1s003," Center for Drug Evaluation and Research, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/2044850Orig1s003.pdf.

64 "Endo Announces Issuance of Vasostrict® Patent," PR Newswire, https://www.prnewswire.com/news-releases/endo-announces-issuance-of-vasostrict-patent-300291415.html (viewed December 6, 2020).

65 "Endo Announces Issuance of Vasostrict® Patent," PR Newswire, https://www.prnewswire.com/news-releases/endo-announces-issuance-of-vasostrict-patent-300291415.html (viewed December 6, 2020).

66 Endo 2018 10-K, at p. 9.

38. The FDA has approved Par Sterile Products to market Vasostrict in five strengths, only the first two of which have been marketed to date, and the first one of which comprises the vast majority of total Vasostrict sales:[67]

- "20UNITS/ML (20UNITS/ML);"
- "200UNITS/10ML (20UNITS/ML);"
- "20UNITS/ML (0.2UNITS/ML);"
- "40UNITS/100ML (0.4UNITS/ML);" and
- "60UNITS/100ML (0.6UNITS/ML)."

39. Over the years, Vasostrict has generated substantial revenues for Plaintiffs. [redacted][68] Through the first nine months of 2021, Vasostrict accounted for over [redacted] percent of Endo's revenues from "Sterile Injectable" products.[69] It is expected that, in 2021, over [redacted] of

67 "Drugs@FDA: FDA-Approved Drugs," FDA, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=204485 (viewed December 7, 2021). *See* Tab 20.

68 Tab 4 [redacted] and Tab 6.

69 Endo 3Q 2021 10-Q, at p. 12. Calculated as [redacted]

Endo's company-wide earnings before interest, taxes, depreciation, and amortization ("EBITDA") will have been generated by Vasostrict.[70]

2. Approved 505(b)(2) Product

40. On March 29, 2020, American Regent, Inc. ("American Regent") submitted NDA No. 212593 to the FDA for marketing approval covering a vasopressin injection product referencing Par Sterile Products' Vasostrict vasopressin.[71] On August 3, 2020, American Regent received FDA approval for its application.[72] The FDA has approved American Regent to market its vasopressin injection product in the "20UNITS/ML (20UNITS/ML)" strength.[73]

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70 Bradley Declaration, at ¶¶ 6-8.

71 "NDA 212593," FDA, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/212593Orig1s000ltr.pdf.

72 "NDA 212593," FDA, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/212593Orig1s000ltr.pdf; I understand that Par Pharmaceuticals reached a settlement agreement with American Regent in May 2020 in regard to general versions of Vasostrict®. Additional settlements were reached with Sandoz, Amphastar Pharmaceuticals, and Fresenius in June, August, and September 2020, respectively. *See* Endo International PLC SEC Form 10-Q for the quarterly period ended September 30, 2020, at p. 31

73 "Drugs@FDA: FDA-Approved Drugs," FDA, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=212593 (viewed December 6, 2020).

41. American Regent's NDA was submitted "pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA)."[74] I understand that a 505(b)(2) application is a "hybrid between an ANDA […] and full NDA."[75] Drugs approved through 505(b)(2) applications "may qualify for three, five or seven years of market exclusivity."[76] In comparison, the first applicant submitting an ANDA can be granted a shorter period of marketing exclusivity. According to the FDA,

> An ANDA applicant must include in its ANDA a patent certification as described in section 505(j)(2)(A)(vii) of the Act. The certification must make one of the following statements: (1) such patent information has not been filed; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed by the manufacture, use, or sale of the drug product for which the ANDA is submitted. The fourth certification is known as a paragraph IV certification. […] In certain circumstances, an applicant who submits the ANDA containing the **first** paragraph IV certification to a patent is protected from competition from other generic versions of the same drug product for 180 days after the earliest of either the initial marketing of the first applicant's drug or a court decision that holds that the

74 "NDA 212593," FDA, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/212593Orig1s000ltr.pdf.

75 "What is 505(b)(2)?," Camargo, https://camargopharma.com/resources/what-is-505b2/ (viewed September 27, 2021).

76 "What is 505(b)(2)?," Camargo, https://camargopharma.com/resources/what-is-505b2/ (viewed September 27, 2021).

patent that is the subject of the This marketing protection is commonly known as **180-day exclusivity**.[77]

42. As discussed in more detail below, American Regent entered into a settlement agreement with Plaintiffs in May 2020, [redacted][78]

43. As noted above, the Eagle Generic was approved yesterday, [redacted]

D. Marketplace

44. I am not a medical doctor. Among other things, and importantly, I rely on the opinions of others who have medical and technical expertise. I provide the description below as background.

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77 "Guidance for Industry 180-Day Exclusivity When Multiple ANDAs Are Submitted on the Same Day," FDA, https://www.fda.gov/media/71304/download ("180-Day Exclusivity Guidance"), at pp. 2-3 (*emphasis added*).

78 *See* section II.D.3.a.

79 "Eagle Pharmaceuticals Announces FDA Maintains Prioritization of ANDA for Vasopressin," Eagle, https://investor.eagleus.com/press-releases/news-details/2021/Eagle-Pharmaceuticals-Announces-FDA-Maintains-Prioritization-of-ANDA-for-Vasopressin/default.aspx (viewed December 4, 2021).

1. Vasodilatory Shock

45. I understand that vasodilatory shock, also known as distributive shock, is a broad term to describe health shocks characterized by abnormally low blood pressure caused by excessive widening of blood vessels.[80] Vasodilatory shock "results from excessive vasodilation [the widening of blood vessels within the body] and the impaired distribution of blood flow."[81] Vasodilation lowers blood pressure and may result in hypotension—as blood vessels widen, the pressure exerted on their walls decreases.[82] During vasodilatory shock, patients are at risk of organ system dysfunction, which may progress to organ failure and death.[83]

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80 "Distributive Shock," StatPearls Publishing LLC, https://www.ncbi.nlm.nih.gov/books/NBK470316/ (viewed November 24, 2021); "Distributive Shock," Medscape, https://emedicine.medscape.com/article/168689-overview#showall (viewed December 3, 2020); "What to Know About Vasodilation," Healthline Media UK Ltd, https://www.medicalnewstoday.com/articles/327402 (viewed December 3, 2020). *See also*, "Prescribing Information," FDA, https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/204485Orig1s000lbl.pdf.

81 "Distributive Shock," Medscape, https://emedicine.medscape.com/article/168689-overview#showall (viewed December 3, 2020); "What to Know About Vasodilation," Healthline Media UK Ltd, https://www.medicalnewstoday.com/articles/327402 (viewed December 3, 2020).

82 "Is Vasodilation Good?" Healthline Media UK Ltd, https://www.healthline.com/health/vasodilation (viewed December 3, 2020); "Understanding Low Blood Pressure -- the Basics," WebMD, https://www.webmd.com/heart/understanding-low-blood-pressure-basics#1 (viewed December 3, 2020).

83 "Distributive Shock," Medscape, https://emedicine.medscape.com/article/168689-overview#showall (viewed December 3, 2020).

46. I understand that there are multiple causes of vasodilatory shock. Septic shock (or sepsis), a life-threatening condition that occurs when blood pressure drops to a dangerously low level after an infection, is the most common cause of vasodilatory shock.[84] Other causes include systemic inflammatory response syndrome due to noninfectious conditions such as pancreatitis, burns, or trauma; toxic shock syndrome; adrenal insufficiency; reactions to drugs or toxins; heavy metal poisoning; hepatic insufficiency; and neurogenic shock.[85] Additionally, after heart surgeries, the heart may not resume proper function, causing blood pressure to decrease to life-threatening levels.[86]

2. Vasodilatory Shock Treatment Options

47. I understand that treatment of vasodilatory shocks requires the reversal of the underlying cause of the shock and the stabilization of the patient's blood pressure.[87] According to the Centers for Disease Control and Prevention

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84 "Septic Shock," NHS, https://www.nhsinform.scot/illnesses-and-conditions/blood-and-lymph/septic-shock (viewed December 3, 2020); "Distributive Shock," Medscape, https://emedicine.medscape.com/article/168689-overview#showall (viewed December 3, 2020).

85 "Distributive Shock," Medscape, https://emedicine.medscape.com/article/168689-overview#showall (viewed December 3, 2020).

86 "Postcardiotomy Cardiogenic Shock," ABIOMED, https://www.abiomed.com/disease-states/postcardiotomy-cardiogenic-shock (viewed December 3, 2020).

87 Lahiry, Sandeep, Sayanta Thakur, and Dwaipayan S. Chakraborty, "Advances in Vasodilatory Shock: A Concise Review," *Indian Journal of Critical Care Medicine*, Vol. 23, No. 10 (2019): 475-480, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6842826/. The term "hemodynamics"

("CDC"), treatment of sepsis entails "[g]iving appropriate treatment, including antibiotics" and "[m]aintaining blood flow to organs."[88] According to the medical literature, "the duration of hypotension before antibiotic treatment has been found to be a critical factor in determining mortality."[89] For patients with hypotension due to sustained septic shock in whom fluid resuscitation does not reverse hypotension, the use of systemic vasopressors (treatments that tighten blood vessels) is indicated to restore blood flow to the heart and brain.[90]

48. I understand that the treatment of vasodilatory shocks (or, more generally, "failure of the cardiovascular system to maintain adequate tissue perfusion") can include "three broad categories: fluid resuscitation, vasopressor therapy, and inotropic therapy."[91] I understand that "fluid resuscitation is usually the

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generally refers to cardiovascular function, such as arterial pressure or cardiac output. Secomb, Timothy, "Hemodynamics," *Comprehensive Physiology*, Vol. 6, No. 2 (2016): 975-1003, at p. 975.

88 "How is Sepsis Diagnosed and Treated?" CDC, https://www.cdc.gov/sepsis/diagnosis/index.html (viewed December 3, 2020).

89 "Distributive Shock," Health Jade, https://healthjade.net/distributive-shock/ (viewed December 6, 2021), citing to Kumar, Anand, *et al*., "Duration of Hypotension Before Initiation of Effective Antimicrobial Therapy is the Critical Determinant of Survival in Human Septic Shock," *Critical Care Medicine*, Vol. 34, No. 6 (2006): 1589-96.

90 "Distributive Shock," Health Jade, https://healthjade.net/distributive-shock/ (viewed December 6, 2021); "What Are Vasopressors?" Everyday Health, Inc., https://www.everydayhealth.com/vasopressors/guide/ (viewed December 3, 2020).

91 Hollenberg, Steven, "Vasoactive Drugs in Circulatory Shock," *American Journal of Respiratory Critical Care Medicine*, Vol. 183 (2011): 847-855 ("Hollenberg (2011)"), at p. 847.

first step."[92] After that, "when fluid administration fails to restore adequate arterial pressure and organ perfusion in patients with shock," vasopressor therapy and / or inotropic therapy "should be initiated."[93] I understand that the goal of vasopressor therapy is to "raise blood pressure," while the goal of inotropic therapy is to "raise cardiac output."[94]

49. I understand that, in vasopressor therapy, norepinephrine and dopamine can be used as a first-line treatment for hypotension.[95] Second-line treatments in vasopressor therapy include epinephrine, phenylephrine, and vasopressin.[96] I understand that treatments in inotropic therapy can include dobutamine, phosphodiesterase inhibitors (including milrinone), and levosimendan.[97]

50. I understand that treatments for vasodilatory shocks may be used in combination. For instance, in 2017, the Society of Critical Care Medicine and the European Society of Intensive Care Medicine published "Guidelines for the Management of Sepsis and Septic Shock," which provides best practices and recommendations based on a consensus committee of 55 international

92 Hollenberg (2011), at p. 847.

93 Hollenberg (2011), at p. 847.

94 Hollenberg (2011), at p. 847.

95 Hollenberg (2011), at pp. 849-51, Table 1.

96 Hollenberg (2011), at pp. 849-51, Table 1.

97 Hollenberg (2011), at pp. 851-52, Table 1.

experts and 25 international organizations.[98] The guidelines recommend adding either vasopressin or epinephrine to norepinephrine in order to raise mean arterial pressure ("MAP") or adding vasopressin to decrease norepinephrine dosage.[99]

51. I understand that vasodilatory shock is an acute condition that typically requires hospital treatment.[100] Vasostrict, which is predominantly used in hospitals, is a well-established drug for treatment of vasodilatory shock and can be, and often is, stocked in hospital crash carts.[101] I understand that Vasostrict is the only FDA-approved branded vasopressin product that is

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98 Rhodes, Andrew, *et al*., "Surviving Sepsis Campaign: International Guidelines for Management of Sepsis and Septic Shock: 2016," *Critical Care Medicine*, Vol. 45, No. 3 (2017): 486-552 ("Rhodes et al (2016)"), at p. 488.

99 Rhodes et al (2016), at p. 504.

100 "Septic Shock Treatment and Management," Medscape, https://emedicine.medscape.com/article/168402-treatment (viewed September 14, 2021). Septic shock is the most common form of vasodilatory shock. Lahiry, Sandeep, Sayanta Thakur, and Dwaipayan S. Chakraborty, "Advances in Vasodilatory Shock: A Concise Review," *Indian Journal of Critical Care Medicine*, Vol. 23, No. 10 (2019): 475-480, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6842826/.

101 *See, e.g.,* "Medical Crash Cart Medications Auto-Replenishment Request for Quote," HealthFirst, https://www.healthfirst.com/medical/crashcart-signup-copy-2/ (viewed November 23, 2021); "A Guide to Crash Carts: Must-Have Features and Medications," Scott-Clark Medical, https://www.scott-clark.com/blog/a-guide-to-crash-carts-must-have-features-and-medications/ (viewed November 23, 2021).

Vasostrict can be removed from refrigeration and stocked in a hospital crash cart for up to 12 months. *See, e.g.,* "Prescribing Information," FDA, https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/204485s011lbl.pdf.

Conversation with Messrs. Bradley, Donatiello, Brown, and Valiga. *See also*, Bradley Declaration, at ¶¶ 5-6, 10-11, 32.

currently marketed in the U.S.[102] As noted above, the Eagle Generic has just been approved and Eagle is poised to launch the product at-risk.[103]

3. Generic Manufacturers

52. In the marketplace for vasopressin, many potential manufacturers have filed ANDAs / 505(b)(2) NDAs referencing Vasostrict. As discussed in more detail below [redacted] while Eagle has stated its intent to launch the Eagle Generic in 2021.[104] There is a wide range of possibilities in terms of the order and timing of the generic launches by different manufacturers.

53. According to Endo's financial disclosure, "beginning in April 2018," eight generic manufacturers sent "notice letters" to Par Sterile Products and Par Pharmaceutical "advising of the filing by such companies of ANDAs / 505(b)(2) NDAs for generic versions of VASOSTRICT® (vasopressin IV

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102 Conversation with Messrs. Bradley, Donatiello, Brown, and Valiga. *See also*, Bradley Declaration, at ¶¶ 9-11.

103 "Eagle Pharmaceuticals Announces FDA Maintains Prioritization of ANDA for Vasopressin," Eagle, https://investor.eagleus.com/press-releases/news-details/2021/Eagle-Pharmaceuticals-Announces-FDA-Maintains-Prioritization-of-ANDA-for-Vasopressin/default.aspx (viewed December 4, 2021).

104 "Eagle Pharmaceuticals Reports Second Quarter 2021 Results," Business Wire, https://www.businesswire.com/news/home/20210809005147/en/Eagle-Pharmaceuticals-Reports-Second-Quarter-2021-Results (viewed November 23, 2021); "Eagle Pharmaceuticals Announces FDA Maintains Prioritization of ANDA for Vasopressin," Eagle, https://investor.eagleus.com/press-releases/news-details/2021/Eagle-Pharmaceuticals-Announces-FDA-Maintains-Prioritization-of-ANDA-for-Vasopressin/default.aspx (viewed December 4, 2021).

solution (infusion)) 20 units/ml and/or 200 units/10 ml."[105] These companies are:

- American Regent;
- Amphastar Pharmaceuticals, Inc. ("Amphastar");
- Aurobindo Pharma Limited ("Aurobindo");
- Dr. Reddy's Laboratories, Inc. ("Dr. Reddy's");
- Fresenius Kabi USA, LLC ("Fresenius");
- Sandoz, Inc. ("Sandoz");
- Eagle, and
- Amneal Pharmaceuticals LLC ("Amneal").[106]

54. Beginning in May 2018, Plaintiffs "filed lawsuits against" six of these eight companies (American Regent, Amneal, Amphastar, Eagle, Fresenius, and Sandoz) "within the 45-day deadline to invoke a 30-month stay of FDA approval pursuant to the Hatch-Waxman legislative scheme."[107] In December 2020, Plaintiffs also sued Dr. Reddy's and Aurobindo.[108]

105 Endo 2020 10-K, at p. 20.

106 Endo 2020 10-K, at p. 20.

107 Endo 2020 10-K, at p. 20.

108 Endo 2020 10-K, at p. 20.

55. From May 2020 through January 2021, Plaintiffs reached settlement agreements with American Regent, Amphastar, Aurobindo, Dr. Reddy's, Fresenius, and Sandoz.[109] As a result, Plaintiffs have dismissed all cases against those six companies.[110]

a. American Regent

56. In May 2020, Plaintiffs entered into a settlement agreement with American Regent ("American Regent Settlement Agreement").[111] [redacted]

57. [redacted]

[redacted]

109 Endo 2020 10-K, at p. 20.

110 Endo 2020 10-K, at p. 20.

111 [redacted]

112 [redacted]

- [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

113 [redacted]

58. As noted above, American Regent received FDA approval for its generic equivalent vasopressin application in August 2020.[114] [redacted]

b. Amphastar

59. In August 2020, Plaintiffs entered into a settlement agreement with Amphastar ("Amphastar Settlement Agreement").[115] [redacted]

114 "NDA 212593," FDA, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/212593Orig1s000ltr.pdf (viewed December 4, 2020); I understand that Par Pharmaceuticals reached a settlement agreement with American Regent in May 2020 in regard to general versions of Vasostrict®. Additional settlements were reached with Sandoz, Amphastar Pharmaceuticals, and Fresenius in June, August, and September 2020, respectively. *See* Endo International PLC SEC Form 10-Q for the quarterly period ended September 30, 2020, at p. 31.

115 [redacted]

[redacted]

61. To date, Amphastar has *not* received FDA approval for its generic vasopressin products.[118] [redacted]

[redacted]

118 "Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations," FDA, https://www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm (viewed December 6, 2021), accessed by searching in FDA Orange Book using "vasopressin" as the active ingredient.

[redacted]

c. Aurobindo

62. In January 2021, Plaintiffs entered into a settlement agreement with Aurobindo ("Aurobindo Settlement Agreement").[120] [redacted]

[redacted]

119 [redacted]

120 [redacted]

64. To date, Aurobindo has *not* received FDA approval for its generic vasopressin products.[123]

123 "Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations," FDA, https://www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm (viewed December 6, 2021), accessed by searching in FDA Orange Book using "vasopressin" as the active ingredient.

[redacted]

d. Dr. Reddy's

66. In January 2021, Plaintiffs entered into a settlement agreement with Dr. Reddy's ("Dr. Reddy's Settlement Agreement").[125] [redacted]

[redacted]

[redacted]

68. To date, Dr. Reddy's has *not* received FDA approval for its generic vasopressin products.[128] [redacted]

[redacted]

128 "Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations," FDA, https://www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm (viewed

[redacted]

e. Fresenius

69. In September 2020, Plaintiffs entered into a settlement agreement with Fresenius ("Fresenius Settlement Agreement").[129] [redacted]

[redacted]

December 6, 2021), accessed by searching in FDA Orange Book using "vasopressin" as the active ingredient.

[redacted]

- [redacted]

71. To date, Fresenius has *not* received FDA approval for its generic vasopressin products.[132] [redacted]

[redacted]

132 "Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations," FDA, https://www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm (viewed December 6, 2021), accessed by searching in FDA Orange Book using "vasopressin" as the active ingredient.

f. Sandoz

72. In June 2020, Plaintiffs entered into a settlement agreement with Sandoz ("Sandoz Settlement Agreement").[133]

- [redacted]

74. To date, Sandoz has *not* received FDA approval for its generic vasopressin products.[137] [redacted]

[redacted]

136 [redacted]

137 "Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations," FDA, https://www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm (viewed December 6, 2021), accessed by searching in FDA Orange Book using "vasopressin" as the active ingredient.

[redacted]

[redacted]

[redacted]

g. Eagle

76. In April 2018, Eagle announced that "it has submitted [,] and the U.S. Food and Drug Administration (FDA) has accepted for filing its abbreviated new drug application (ANDA) for vasopressin injection, 1ml."[139] In February 2021, the FDA sent Eagle a Complete Response Letter ("CRL") for its ANDA for vasopressin.[140] The FDA maintained Priority Review for Eagle's ANDA for vasopressin and assigned a Generic Drug User Fee Amendments date of

139 "Eagle Pharmaceuticals' Vasopressin ANDA Accepted for Filing by the FDA," Eagle Pharmaceuticals, https://www.sec.gov/Archives/edgar/data/827871/000110465918024064/a18-10132_1ex99d1.htm (viewed November 24, 2021).

140 *See* "Eagle Pharmaceuticals Reports Second Quarter 2021 Results," Eagle Pharmaceuticals, https://investor.eagleus.com/press-releases/news-details/2021/Eagle-Pharmaceuticals-Reports-Second-Quarter-2021-Results/default.aspx (viewed November 23, 2021).

December 15, 2021.[141] According to an Eagle press release in August 2021, it expects a commercial launch of the Eagle Generic by the end of 2021.[142]

h. Amneal

77. According to Plaintiffs, Amneal has submitted ANDA No. 212944 (the "Amneal Single-Dose ANDA"), "seeking approval to engage in the commercial manufacture, use, and sale of a proposed generic Vasopressin Injection USP, 20 units/1 mL (20 units/mL) product."[143] In addition, Amneal has submitted ANDA No. 212945 (the "Amneal Multi-Dose ANDA"), "seeking approval to engage in the commercial manufacture, use, and sale of a proposed generic Vasopressin Injection USP, 200 units/10 mL (20 units/mL)."[144] According to Amneal, as of August 2021, Amneal was "working with FDA on the CRL" related to its vasopressin ANDAs, and

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141 *See* "Eagle Pharmaceuticals Reports Second Quarter 2021 Results," Eagle Pharmaceuticals, https://investor.eagleus.com/press-releases/news-details/2021/Eagle-Pharmaceuticals-Reports-Second-Quarter-2021-Results/default.aspx (viewed November 23, 2021). *See also*, https://investor.eagleus.com/press-releases/news-details/2021/Eagle-Pharmaceuticals-Announces-FDA-Maintains-Prioritization-of-ANDA-for-Vasopressin/default.aspx (viewed December 4, 2021).

142 "Eagle Pharmaceuticals Reports Second Quarter 2021 Results," Eagle Pharmaceuticals, https://investor.eagleus.com/press-releases/news-details/2021/Eagle-Pharmaceuticals-Reports-Second-Quarter-2021-Results/default.aspx (viewed November 23, 2021).

143 "Complaint," 1:19-cv-00712, April 18, 2019 ("Complaint v. Amneal"), at pp. 9-10.

144 Complaint v. Amneal, at p. 10.

Amneal "expect[ed] to respond in the third quarter" of 2021.[145] According to Amneal, responding to FDA's CRL in time will "put[] [Amneal] on a path to have approval as soon as the first half of 2022."[146]

III. INJUNCTIVE RELIEF ANALYSIS

A. Framework

78. In determining whether to grant preliminary injunctive relief, I understand that courts consider four factors: 1) the likelihood of the moving party's success on the merits, 2) the irreparable harm that would occur to the moving party without relief, 3) the balance of the hardships, and 4) the impact on the public interest.[147] I have been asked to address economic issues relating to factors 2 through 4, with particular emphasis on factor 2.

B. Irreparable Harm

79. In evaluating "irreparable harm," a critical starting point is an understanding of how harm suffered by a patent holder can be considered "irreparable" when

145 "Amneal Pharmaceuticals, inc (AMRX) Q2 2021 Earnings Call Transcript," The Motley Fool, https://www.fool.com/earnings/call-transcripts/2021/08/09/amneal-pharmaceuticals-inc-amrx-q2-2021-earnings-c/ (viewed September 27, 2021).

146 "Amneal Pharmaceuticals, inc (AMRX) Q2 2021 Earnings Call Transcript," The Motley Fool, https://www.fool.com/earnings/call-transcripts/2021/08/09/amneal-pharmaceuticals-inc-amrx-q2-2021-earnings-c/ (viewed September 27, 2021).

147 *Winter v. Natural Resources Defense Council, Inc.*, 129 S. Ct. 365, 376, 172 L. Ed. 2d 249, 67 Env't. Rep. Cas. (BNA) 1225 (2008); *Chrysler Motors Corp. v. Auto Body Panels of Ohio, Inc.*, 908 F.2d 951, 953-54, (Fed. Cir. 1990).

injured parties who are entitled to damages can be awarded monetary compensation following a trial on the merits. Over time, economic analysis, in conjunction with a wide array of court opinions, suggests that there is a reasonable and workable test for irreparable harm in patent cases. That test suggests an evaluation of five factors:

- **Existence of harm**—is there likely to be harm?;[148]
- **Preservation of status quo**—will lack of an injunction unreasonably disrupt the status quo?;[149]
- **Causal nexus**—does the harm flow from the infringement?;[150]
- **Quantifiability**—can all of the likely harm be quantified with a reasonable degree of economic certainty?;[151] and
- **Collectability**—are there any impediments to the patent holder's recovery of payment for that harm?[152]

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148 *See also, LEGO v. ZURU Inc.*, 799 Fed. Appx. 823, 834, 836 (Fed. Cir. 2020); *Palmer v. Connecticut Railway & Lighting Co.*, 311 U.S. 544, 561 (1941); *Story Parchment Co. v. Patterson Parchment Paper Co.*, 282 U.S. 555, 562 (1931).

149 *See, e.g., Cordis Corp. v. Medtronic, Inc.*, 835 F.2d 859 (Fed. Cir. 1987). *Atlas Powder Co. v. Ireco Chemicals*, 773 F.2d 1230 (1985). *Atlas Powder Co. v. Ireco Chemicals*, 773 F.2d 1230, 1231 (Fed. Cir. 1985). *Continental Service Group, Inc. v. United States*, 722 Fed. Appx. 986 (2018).

150 *See, e.g., Apple Inc. v. Samsung Electronics Co., Ltd.*, 678 F. 3d 1314, 1324 (Fed. Cir. 2012).

151 *See, e.g., LEGO v. ZURU Inc.*, 799 Fed. Appx. 823. 833 (Fed. Cir. 2020); *Broadcom Corp. v. Qualcomm, Inc.*, 543 F.3d 683, 703 (Fed. Cir. 2008).

152 *See, e.g., Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142 (Fed. Cir. 2011).

1. Existence of Harm

80. The FDA has just approved the Eagle Generic, and based on its public statements announcing an intent to launch its Generic before the end of 2021, Eagle is likely to promptly launch its generic at-risk as a direct competitor to Vasostrict and to continue selling its Generic, if injunctive relief is not granted. [redacted]

81. Accordingly, absent injunctive relief, generic entry by Eagle is imminent [redacted]

[redacted]

[redacted]

83. Generic pharmaceutical entry almost always leads to an immediate reduction in the shipments of the branded equivalent. For retail pharmacy or oral drugs, prescriptions that would have been written and filled with the branded drug often are switched to the generic product.[154] Similarly, and as discussed in more detail below, for institutional (*e.g.*, hospital) or injectable drugs, like those at issue here, generics compete with branded drugs by offering substantially lower prices for orders from distributors (such as group purchasing organizations ("GPOs")), who often switch from branded drugs to generics to fulfill orders from institutions.

84. The economics literature shows that brand unit shares generally decline, on average, anywhere from 50 to 90 percent within one year of generic entry and, in some cases, can decline more than 90 percent within the *first six months*

154 *See* Caves, Richard, *et al.*, "Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry," *Brookings Papers on Economic Activity: Microeconomics*, Vol. 1991 (1991): 1-66 ("Caves et al (1991)"); Aitken, Murray L., *et al.*, "The Regulation of Prescription Drug Competition and Market Responses: Patterns in Prices and Sales Following Loss of Exclusivity," *National Bureau of Economic Research Working Paper* No. 19487 (2013): 1-37 ("Aitken et al (2013)"); Grabowski, Henry, *et al.*, "Updated Trends in US Brand-Name and Generic Drug Competition," *Journal of Medical Economics*, Vol. 19, No. 9 (2016): 836-844 ("Grabowski et al (2016)").

after generic entry.[155] A 2016 study showed that branded drugs' average unit shares tend to fall by 88 percent within one year following generic entry, though there is a fair amount of variation around that average.[156] The same study also showed that, for branded drugs with annual sales exceeding $250 million (which Vasostrict far surpasses), *average* unit shares tend to fall by 93 percent within one year.[157]

85. Based on the range of generic penetration rates discussed in the economics literature, the anticipated revenue impact of generic entry on Vasostrict would be substantial. [redacted]

[redacted]

155 Grabowski, Henry, "Are the Economics of Pharmaceutical Research and Development Changing? Productivity, Patents and Political Pressures," *Pharmacoeconomics*, Vol. 22, Suppl. 2 (2004): 15-24 ("Grabowski (2004)") (describing the impact of generic entry on prescription shares); Saha, Atanu, *et al.*, "Generic Competition in the US Pharmaceutical Industry," *International Journal of the Economics of Business*, Vol. 13, No. 1 (2006): 15-38 ("Saha et al (2006)"); Silver, Richard, "A Wall Street Perspective on Generics," 2007 EGA Annual Conference, Lehman Brothers (June 14-16, 2007) ("Silver (2007)"); Danzon, Patricia, and Michael F. Furukawa, "Cross-National Evidence on Generic Pharmaceuticals: Pharmacy vs. Physician-Driven Markets," *National Bureau of Economic Research Working Paper* No. 17226 (2011): 1-44 ("Danzon et al (2011)"), at p. 31; Grabowski et al (2016), at p. 843.

156 Grabowski et al (2016), at p. 843.

157 The authors studied new molecular entities experiencing initial generic entry in the most recent years of the authors' sample, 2013–2014, and with sales greater than $250 million (in 2008 dollars) in the year prior to initial generic entry. Grabowski et al (2016), at pp. 836, 840, 843.

[redacted]

86. To illustrate the approximate magnitude and *wide range* of the potential impact, I apply estimates (averages) from the economics literature to historical Vasostrict U.S. unit sales and revenues.[160] Over the *twelve months* following initial generic entry, the revenue impact on Vasostrict could range from a low of approximately [redacted] to a high of approximately [redacted][161] As I discuss below, the large magnitude of the potential impact, and the substantial uncertainty around the precise level of that impact, likely would lead to severe effects on Plaintiffs' and Endo's financial viability and flexibility, research and development ("R&D"), access to capital, and employment.

87. The economics literature shows that both the magnitude and penetration of generic sales, in general, increase with the number of generics in the

158 [redacted]

160 Tab 25.

161 Tab 25.

marketplace.[162] Researchers have shown that, in a marketplace with one generic entrant (*e.g.*, Eagle), the generic unit share ranges from a low of 1 percent to a high of 97 percent, with the average of approximately 39 percent, within one year after the generic entry.[163] According to a 2020 study, if only one generic enters and reaches 39 percent in unit share, [redacted]

162 *See, e.g.,* Saha et al (2006); Saha, Atanu, and Heather Roberts, "Pharmaceutical Industry's Changing Market Dynamics," *International Journal of the Economics of Business*, Vol. 27, No. 2 (2020): 159-175 ("Saha et al (2020)").

163 Saha et al (2006), Table 1. Calculated as 38.5 percent = (10% + 46% + 97% + 1%) / 4.

[redacted] [redacted]

[redacted] [redacted]

[redacted] The full harm that will be suffered by Plaintiffs and Endo could flow from the direct losses (in Vasostrict revenues) and the indirect losses (in financial viability / flexibility, R&D, access to capital, and employment) due to Eagle's at-risk launch [redacted]

88. Generic entry almost always affects prices. Generic products compete on price and usually are priced substantially below the branded equivalent because generic pharmaceutical companies do not incur the same R&D, regulatory, and marketing costs as an innovator company.[166] Studies have shown that, on average, generic prices are substantially lower than pre-entry brand prices at various points in time (*e.g.*, within one year after generic entry), and decline with increased generic competition. Among drugs experiencing initial generic entry between 2015 and 2017, generic prices typically were 38 to 65 percent lower than pre-entry brand prices when two generics entered, 75 to 92 percent lower when five generics entered, and 98 to 99 percent lower when ten or more entered.[167]

166 Grabowski et al (2016), at p. 836.

167 Based on 25th and 75th percentile values for the generic-to-brand ratio of average manufacturer price. Conrad, Ryan, and Randall Lutter, "Generic Competition and Drug

89. While some economic studies may show that branded drug prices can increase upon generic entry, these studies tend to analyze retail pharmacy drugs or oral drugs.[168] However, the marketplace dynamics of retail pharmacy drugs or oral drugs differ from that of institutional (*e.g.*, hospital) drugs or injectables, as is at issue here. As noted by Professors Grabowski and Vernon, "injectables are sold almost exclusively to hospitals where the degree of brand loyalty is considerably less." [169] They found that "the more prevalent pattern is for the incumbent firm to cut prices in the face of generic competition."[170]

Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices," U.S. Food & Drug Administration Report (December 2019): 1-9 ("Conrad et al (2019)"), at pp. 2, 9. Earlier studies in the economics literature also have established that prices tend to decline with increased generic competition. For example, one study found that, as the number of generic entrants increases, the size of the manufacturers' discounts (*i.e.*, price reductions) increases. Cook, Anna, "How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry," The Congress of the United States Congressional Budget Office Study (July 1998) ("Cook (1998)"), at pp. 62-63. *See also*, Danzon et al (2011), at p. 30; Saha et al (2006), at p. 28.

168 *See, e.g.,* Saha et al (2006), Caves et al (1991), Aitken et al (2013), Frank, Richard G., and David S. Salkever, "Pricing, Patent Loss and the Market for Pharmaceuticals," *Southern Economic Journal*, Vol. 59, No. 2 (1992): 165-179 ("Frank et al (1992)"), at p. 165, and Grabowski, Henry G., and John Vernon, "Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Drug Act," *The Journal of Law & Economics*, Vol. 35, No. 2 (1992): 331-350 ("Grabowski and Vernon (1992)").

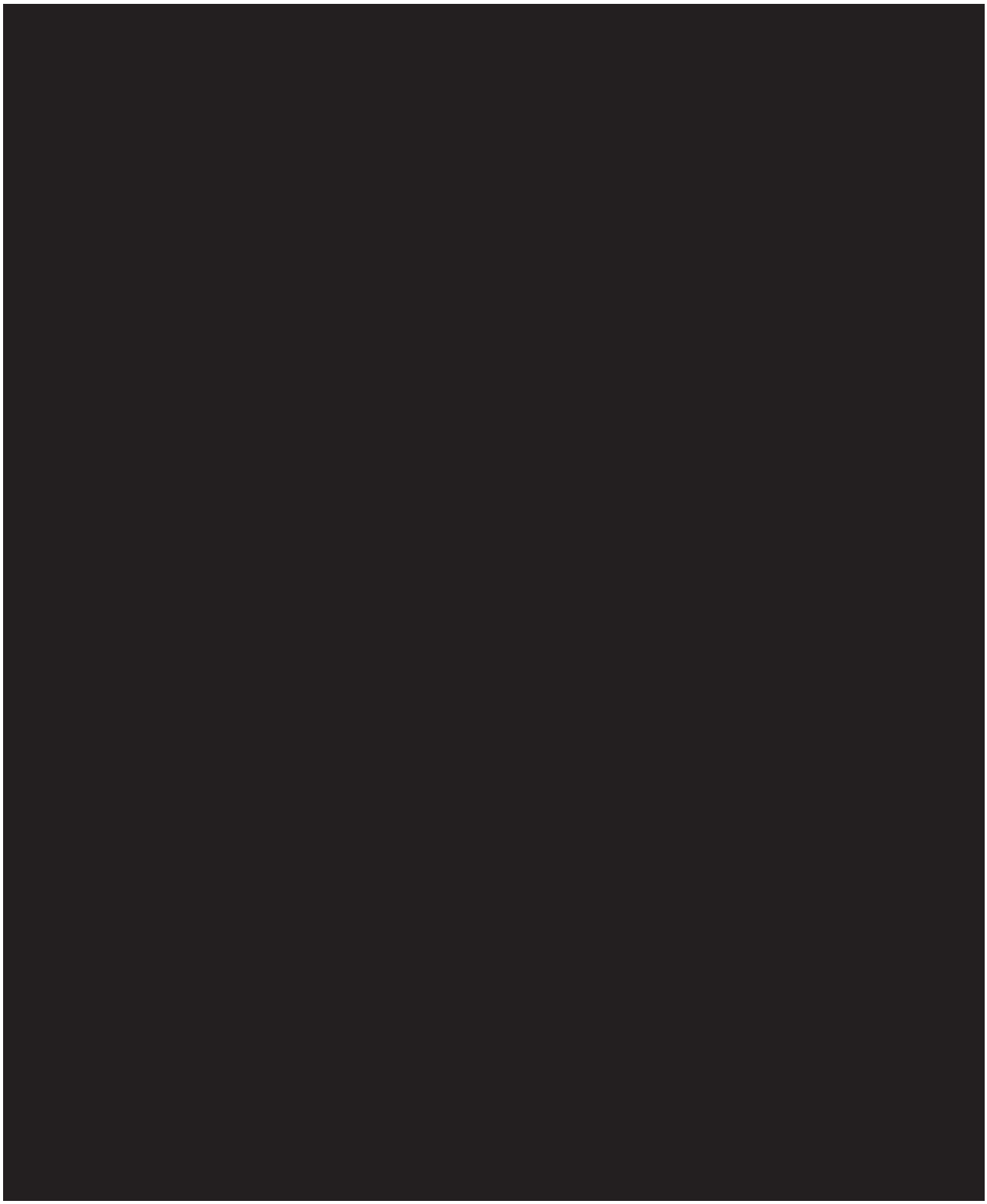
169 Grabowski and Vernon (1992), at p. 340.

170 Grabowski and Vernon (1992), at p. 340. In addition, economic research has demonstrated that generic entry causes decreases in price for branded drugs that are associated with a high percentage of third-party payments because "many managed care organizations encourage generic substitution in order to cut costs." *See* Regan, Tracy L., "Generic Entry, Price Competition, and Market Segmentation in the Prescription Drug Market," *International Journal of Industrial Organization*, Vol 26 (2008): 930-948, at p. 946.

90. A useful example of this phenomenon is in the marketplaces for palonosetron and dexmedetomidine, which have experienced generic entry in recent years. Both palonosetron and dexmedetomidine are hospital / institutional drugs.[171] In both marketplaces, branded drug prices (Aloxi® ("Aloxi") for palonosetron and Precedex® ("Precedex") for dexmedetomidine) decreased substantially upon generic entry. [redacted]

171 *See, e.g.,* "Dexmedetomidine," Drugs.com, https://www.drugs.com/mtm/dexmedetomidine.html (viewed November 23, 2021); "Palonosetron Injection," MedlinePlus, https://medlineplus.gov/druginfo/meds/a610002.html (viewed December 6, 2021).

172 [redacted]



174 Tab 15.

175 Tab 12.

91. As noted above, vasopressin (*i.e.*, currently, Vasostrict) is predominantly used in hospitals, and primarily purchased through GPOs.[176] Upon entry, generic vasopressin manufacturers will compete for contracting with GPOs by pricing their products at substantially lower levels than Vasostrict.[177] I understand that such pricing strategies may be driven, in part, by the fact that most of the generic vasopressin manufacturers, upon entry, have not established track records for being reliable suppliers of vasopressin, and hence may need to offer their products at substantially lower price levels than Vasostrict to entice contracting from GPOs.[178]

92. Facing competition from the generics, Plaintiffs likely will be forced to, perhaps substantially, lower the price for Vasostrict to maintain its current position with GPOs. [redacted] Plaintiffs and Endo likely will suffer substantial harm due to price erosion after generic entry. [redacted]

176 Conversation with Messrs. Bradley, Donatiello, Brown, and Valiga. *See also*, Bradley Declaration, at ¶¶ 10-12.

177 Conversation with Messrs. Bradley, Donatiello, Brown, and Valiga. *See also*, Bradley Declaration, at ¶¶ 22-24.

178 Conversation with Messrs. Bradley, Donatiello, Brown, and Valiga.

179 [redacted]

[redacted]

2. Preservation of Status Quo

93. I understand that, unlike a permanent injunction, which is an equitable remedy awarded to an injured patentee, a preliminary injunction is a form of relief that is imposed by a court to preserve the status quo during litigation.[180] Preliminary injunctions are authorized under Federal Rule of Civil Procedure 62(d), which states that "[while] an appeal is pending from an interlocutory order or final judgment that grants, continues, modifies, refuses, dissolves, or refuses to dissolve or modify an injunction, the court may suspend, modify,

[180] *See United Mine Workers v. International Union, United Mine Workers*, 412 F.2d 165, 168 (D.C. Cir. 1969); *Quon v. Stans*, 309 F. Supp. 604, 607 (N.D. Cal. 1970). *Cordis Corp. v. Medtronic, Inc.*, 835 F.2d 859, 863 (Fed. Cir. 1987). *Atlas Powder Co. v. Ireco Chemicals*, 773 F.2d 1230 (1985). *Continental Service Group, Inc. v. United States*, 722 Fed. Appx. 986, 994-995 (Fed. Cir. 2018).

restore, or grant an injunction on terms for bond or other terms that secure the opposing party's rights."[181] The Federal Circuit has written

> [preserving the status quo] is of particular relevance for patent property, for the patent term continues to run during litigation, and a loss of patent-supported exclusivity during the years of litigation may exhaust not only the life of the patent, but also the value of the invention to its creator.[182]

94. In this matter, preliminary injunctive relief will preserve the status quo that exists now, just prior to Eagle's anticipated at-risk launch absent the issuance of injunctive relief. That is, Plaintiffs would remain the sole provider of FDA-approved vasopressin, as they have been for the past seven years or so. If a preliminary injunction is issued, Eagle would await entry until the appeals court has rendered its decision.

95. As discussed in more detail below, disruption of the status quo (i.e., allowing for competitive entry) could result in a substantial reduction in Plaintiffs' and Endo's cash flows, which Plaintiffs and Endo rely upon for their overall

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181 Fed. R. Civ. P. 62(d). *See also*, *United States v. Criminal Sheriff*, 19 F.3d 238, 239 (5th Cir. 1994).

182 *Kimberly-Clark v. First Quality Baby Prod.*, 660 F.3d 1293, 100 U.S.P.Q.2d (BNA) 1299-1300 (Fed. Cir. 2011). *See also Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981) ("The purpose of a preliminary injunction is merely to preserve the relative positions of the parties until a trial on the merits can be held."); *Smith Int'l, Inc. v. Hughes Tool Co.*, 718 F.2d 1573, 1578 (Fed. Cir. 1983) ("A preliminary injunction will normally issue only for the purpose of preserving the status quo and protecting the respective rights of the parties pending final disposition of the litigation.").

business operations (such as maintaining Vasostrict inventories).[183] Preserving the status quo will maintain cash flows and corresponding stable inventories of Vasostrict at Endo and at Endo's customers, which include wholesalers and hospitals.[184] Considering the emergency use nature of Vasostrict in treating COVID-19 patients,[185] maintaining stable levels of Vasostrict inventory serves the interest of the public. Preserving that status quo will also maintain the manufacturing throughput of Plaintiffs and Endo and, ultimately, their financial position.

3. Causal Nexus

96. I understand that a determination of irreparable harm requires a finding that there is a "sufficiently strong causal nexus [that] relates the alleged harm to the alleged infringement."[186] In this case, and potentially in other cases where the alleged infringer is poised to launch or has launched its generic product with an approved ANDA, the requirement for causal nexus can be easily satisfied.

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183 Endo International PLC SEC Form 10-Q for the quarterly period ended June 30, 2021 ("Endo 2Q 2021 10-Q"), at pp. 34-35, 51. *See also*, Bradley Declaration, at ¶¶ 6-8, 39-40.

184 Endo 2Q 2021 10-Q, at pp. 34-35.

185 Poston, Jason T., Bhakti K. Patel, and Andrew M. Davis, "Management of Critically Ill Adults with Covid-19," *Jama*, Vol. 323, No. 18 (2020): 1839-1841.

186 *Apple Inc. v. Samsung Elecs. Co.*, 695 F.3d 1370, 1374-75 (Fed. Cir. 2012).

97. Eagle's Generic ANDA references Vasostrict "as the reference listed drug."[187] As noted above, Plaintiffs' Patents at Issue are embodied in Vasostrict.[188] Further, I understand that Eagle would not be permitted to sell its generic vasopressin product if it were to be found to infringe the Patents at Issue.[189]

98. Thus, if Plaintiffs were to prevail on appeal, Eagle would not have an FDA-approved product without having infringed the Patents at Issue, and it is Eagle's FDA-approved product that is the source of the infringement harm to Plaintiffs. There is a strong causal nexus that "relates the alleged harm to the alleged infringement."

4. Quantifiability

99. Generally, the quantification of economic harm in a case like this involves a comparison of the alleged injured party's (here, Plaintiffs') condition in the world *without* generic at-risk launch by Eagle and the injured party's condition in the world *with* the (continued) generic at-risk launch by Eagle.[190] Any diminishment in the injured (here, branded) company's condition

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187 Complaint v. Eagle, at p. 7.

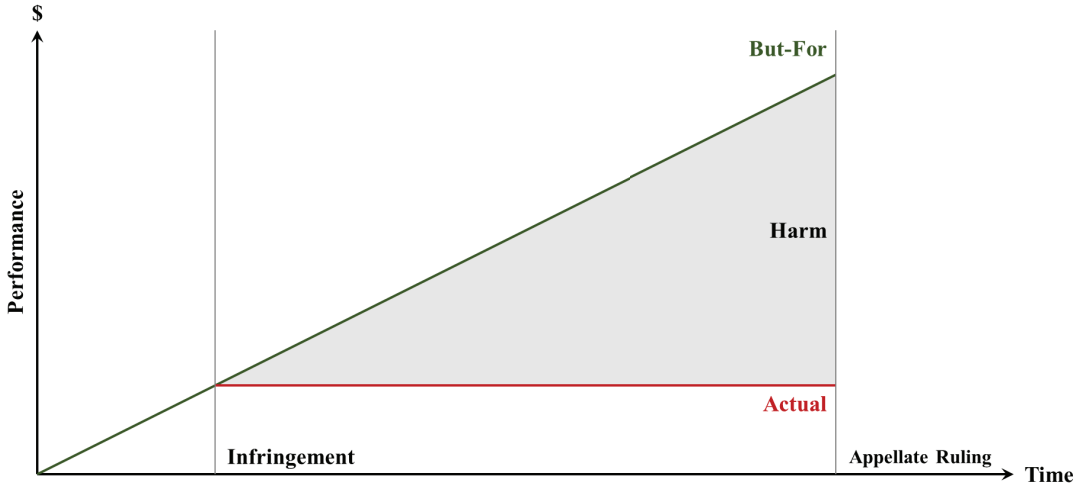
188 Endo International PLC SEC Form 10-K for the fiscal year ended December 31, 2018 ("Endo 2018 10-K"), at p. 9.

189 *See* 35 U.S.C. § 271(e)(4).

190 The difference between these two worlds specifically captures the harm attributable to Eagle's Generic.

between those worlds represents the injured company's harm attributable to the allegedly unlawful action (generic entry), holding other things constant. This is illustrated in Figure 3 below.

Figure 3: Illustration of Harm



100. To be awarded monetary damages for any harm that is incurred, the harm must be quantifiable (*i.e.*, reducible to a monetary value) with a reasonable degree of accuracy and certainty such that the magnitude of harm can be adequately measured. If such a calculation cannot be made for *all* of the harm suffered by the injured company, then the injured company will not be able to receive adequate monetary compensation for that harm. In that case, issuance of an injunction may be appropriate.[191]

[191] *Automated Merchandising Sys., Inc. v. Crane Co.*, 357 F. App'x. 297, 300-301 (Fed. Cir. 2009).

101. Whether an injured party's harm is considered "irreparable" depends on the facts of each case.[192] Examples of types of harm that have been found to be irreparable include loss of sales, price erosion, loss of market share, loss of business opportunities, and loss of goodwill.[193]

102. For a variety of reasons, harm suffered by an injured company may not be fully compensable with monetary damages. One possible impediment is that there may be too much uncertainty to estimate how the injured / branded company would have performed in a world where the challenged generic at-risk launch had not occurred (the green line above). That is, though there will be, at the point of a final resolution of the case, developed evidence as to the branded company's performance in the actual (generic at-risk launch by Eagle prior to resolution of Plaintiffs' appeal) world (the red line above), there may be substantial uncertainty as to how well the branded company would have performed if there had been no generic launch by Eagle. Significant

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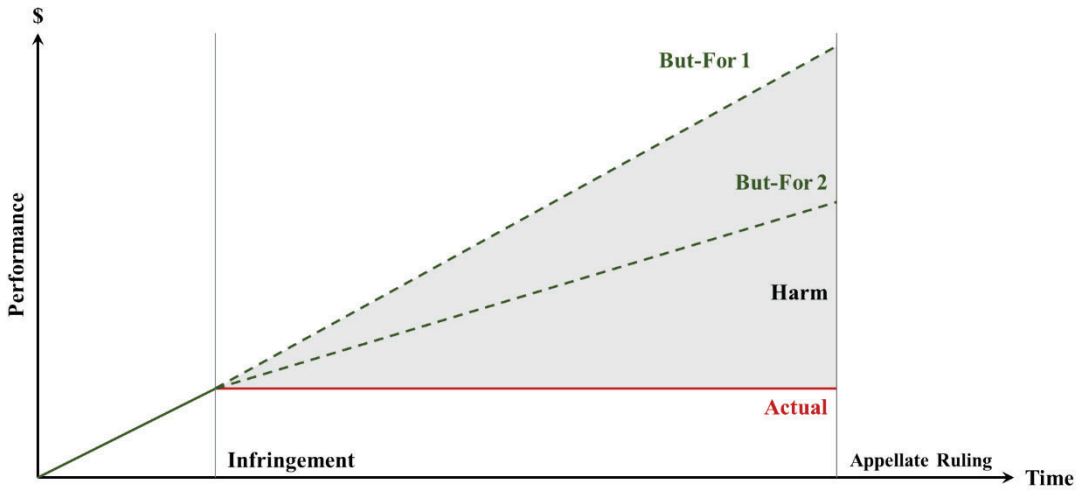
192 The Court of Appeals for the Federal Circuit noted in *Celsis In Vitro, Inc. v. Cellzdirect, Inc.* 664 F.3d 922, 930 (Fed. Cir. 2012), that "[p]rice erosion, loss of goodwill, damage to reputation, and loss of business opportunities are all valid grounds for finding irreparable harm," and upheld a district court's granting of a preliminary injunction. In doing so, the Court quoted the following explanation from the district court: "[t]here is no effective way to measure the loss of sales or potential growth—to ascertain the people who do not knock on the door or to identify the specific persons who do not reorder because of the existence of the infringer." *Id*.

193 *Id. See also*, *Canon, Inc. v. GCC Int'l Ltd.*, 263 F. App'x. 57, 62 (Fed. Cir. 2008); *Systemation, Inc. v. Engel Indus., Inc.*, 1999 U.S. App. LEXIS 3849, at *7, *15 (Fed. Cir. 1999); *Henkel Corp. v. Coral, Inc.*, 754 F. Supp. 1280, 1322 (N.D. Ill. 1990).

uncertainty may be found to exist where sales of the technology or technologies in question are new and / or growing at a rapid, but unpredictable rate, where there have been recent shocks (like product recalls, adverse macroeconomic events, or a pandemic) impacting the marketplace, or where there has been new competitive entry. This is illustrated in Figure 4 below, where the dashed green lines illustrate a wide range of possibilities.

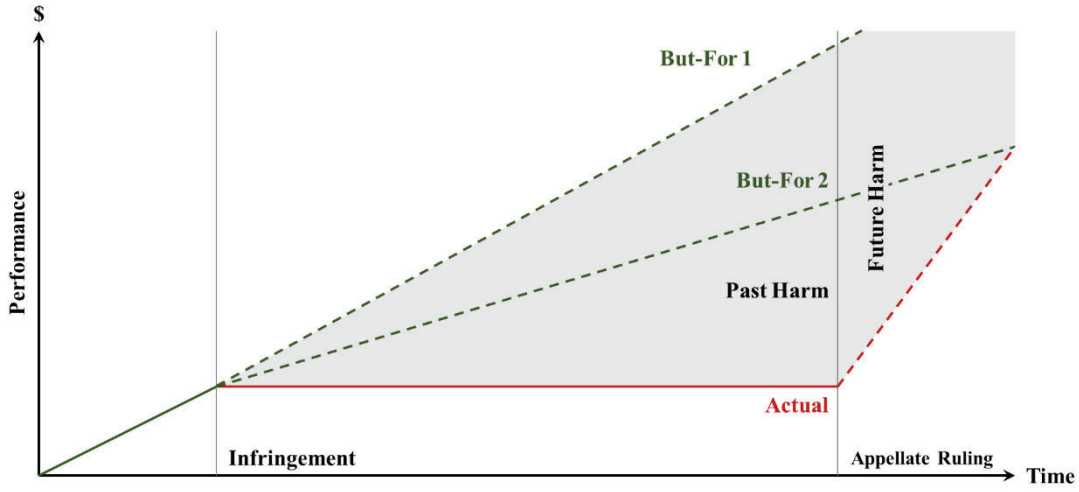
Figure 4: Illustration of Hard-to-Quantify Harm



103. Further complicating any ability to quantify harm with a reasonable degree of certainty is that a generic launch may introduce distortions in the marketplace that alter the long-term development of the marketplace in unpredictable, and potentially irreversible, ways. For example, a generic launch may lead to long-lasting (or even permanent) distortions in pricing (*i.e.*, price erosion) or share, or it may alter the growth trajectory of the branded company in ways that may

be difficult, if even possible, to reverse. If, in fact, the distortions caused by a generic launch are irreversible, or virtually so, the full magnitude of the harm may become incalculable (*e.g.*, due to future uncertainty) or uncollectible (*e.g.*, if open-ended future losses exceed the resources of the generic company). This is illustrated in Figure 5 below, where the dashed line illustrates one possibility.

Figure 5: Illustration of Hard-to-Quantify Past & Future Harm



104. Further, harm may not be compensable if it is not a harm that is typically included in monetary damages awards. Some forms of harm are difficult, if not impossible, to quantify, such as damage to reputation, loss of goodwill, or the loss of potential (but unknown) business opportunities.

105. One type of harm that Plaintiffs here will suffer from Eagle's anticipated generic launch, if unchecked, consists of the loss of revenues (and

corresponding profits) resulting from fewer unit shipments and potentially lower net prices for Vasostrict. It is *possible* that *some* of the direct harm could be adequately quantifiable at a later damages trial. The large magnitude and wide range of the potential direct impacts likely would lead to severe effects on Plaintiffs' financial viability and flexibility, investments in R&D, access to capital, and employment. It is unlikely that any of the indirect harm here will be adequately quantifiable at a later damages trial.

a. Direct Losses

(i) Loss of Unit Shipments

106. [redacted] Although the actual world (red line above) will be known as of the point of a decision resolving Endo's pending appeal, the but-for world (the one with no Eagle

infringement, *i.e.*, the green line above) would be extraordinarily difficult here to assess. That substantially complicates the quantification of harm, which represents the difference between the (unknown and likely unknowable) but-for world and the (known) actual world.

107. In the but-for world, the one with no Eagle infringement, Endo's Vasostrict unit shipments would still be exposed to the macroeconomic conditions in the marketplace. For example, the ongoing COVID-19 pandemic has led to sizeable variations in Vasostrict unit shipments that did not exist before the pandemic. [redacted]

There is substantial uncertainty associated with both the duration and the trajectory of the pandemic (*e.g.*, number of new cases and hospitalizations), both of which can substantially affect demand for vasopressin in the future.

108. [redacted]

194 [redacted]

[redacted]

109. [redacted]

[redacted]

[redacted]

110. Further, even after an appellate decision in favor of the Plaintiffs in this matter, there could be generic inventory leftover in various links in the vasopressin supply chain (*e.g.*, at wholesalers or, more importantly, hospitals). Such pipeline overhang can lead to continuing harm after the litigation. [redacted] While some of Plaintiffs' / Endo's unit shipments losses may be knowable as of the resolution of this matter, the quantification of losses, particularly in the future, will be, at best, complicated and challenging, if not impossible to estimate.

(ii) Price Erosion

111. An at-risk launch of Eagle's Generic, if unchecked, likely would affect Plaintiffs' ability to maintain price and access. As discussed above, in the vasopressin marketplace, many generic manufacturers (at least eight, including Amneal) have submitted ANDAs / 505(b)(2) NDAs for generic

[redacted]

vasopressin. As noted above, vasopressin is predominantly an institutional drug and, currently, the vast majority of Vasostrict sales are to hospitals. In general, hospitals purchase Vasostrict through GPOs. [redacted] To sustain its business and contracting relationship with GPOs, Plaintiffs, in turn, likely would need to reduce the price of Vasostrict to keep customers and maintain some level of sales. These price reductions would likely include price concessions to institutional purchasers to encourage continued use of branded Vasostrict. [redacted] In fact, Eagle's entry could lead to frequent downward adjustments in the Vasostrict price.

112. It may be difficult, at best, to determine at what price Plaintiffs would have sold Vasostrict but for Eagle's at-risk launch of its Generic. While the actual trajectory of prices and discounts will be known as of the point of resolution, Vasostrict's difference in trajectories between the worlds *with* versus *without* the generic launch by Eagle would be exceedingly difficult to estimate. The unpredictability of prices that will be realized in a future but-for marketplace

[redacted]

reflects the unpredictability of demand [redacted] It is a fundamental economic principle that demand fluctuations, all else equal, can result in price changes.[201] As discussed above, the demand for vasopressin in the future is associated with a variety of uncertainties, which can lead to substantial unpredictability in vasopressin price.

113. Even if the difficulties of estimation did not exist, it is unlikely that Plaintiffs could achieve a restoration of prices after a decision on appeal because the presence of a generic [redacted] would fundamentally alter customers' pricing expectations and institutional purchasers' negotiating positions. [redacted] It is well documented in the economics literature that negotiating parties (*e.g.*, GPOs) have the tendency to maintain their positions around outcomes that have been achieved before

[201] *See, e.g.,* Mankiw, N. G., *Principles of Economics* (2011), Sixth Edition, South-Western Cengage Learning, at p. 79.

(*e.g.*, lower vasopressin prices after Eagle's at-risk launch).[202] Purchasers (*e.g.*, GPOs) often put more weight on a loss (an unexpected price increase) than on a gain (a price decrease) of the same magnitude, and hence can experience price increase as a loss that is larger than the gain they would experience from the initial price decrease upon an Eagle at-risk launch.[203] Although price *reductions* often are easy to implement across a wide variety of businesses and products, price *increases* are more difficult to achieve—in other words, prices can be "sticky upward."[204] To the extent there is price stickiness in this case, any immediate reductions in net price would likely be

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202 *See* Kahneman, Daniel, and Amos Tversky, "Judgment under Uncertainty: Heuristics and Biases," *Science*, Vol. 185 (1974): 1124-1131 ("Kahneman Tversky (1974)"); Kahneman, Daniel, Jack Knetsch, and Richard Thaler, "Anomalies: The Endowment Effect, Loss Aversion, and Status Quo Bias," *Journal of Economic Perspectives*, Vol. 5, No. 1 (1991): 193-206; Kahneman, Daniel, "Reference Points, Anchors, Norms, and Mixed Feelings," *Organizational Behavior and Human Decision Processes*, Vol. 51 (1992): 296-312; Ames, Daniel R., and Malia Mason, "Tandem Anchoring: Informational and Politeness Effects of Range Offers in Social Exchange," *Journal of Personality and Social Psychology,* Vol. 108, No. 2 (2015): 254-274.

203 *See* Kahneman, Daniel, and Amos Tversky, "Prospect Theory: An Analysis of Decision Under Risk," *Econometrica*, Vol. 47 (1979): 263-292; Kalwani, Manohar U., *et al.*, "A Price Expectations Model of Customer Brand Choice," *Journal of Marketing Research*, Vol. 27 (1990): 251-262.

204 For example, research has shown that businesses often try to avoid outright price increases, and that they expect consumers to react more negatively to price increases than economic theory would predict if consumers were behaving rationally. Gourville, John T., and Jonathan J. Koeler, "Downsizing Price Increases: A Greater Sensitivity to Price than Quantity in Consumer Markets," *Harvard Business School Marketing Research Papers* (June 2004). Recent increases in the price of drugs have generated some negative media coverage and even a hearing in the United States Senate. *See, e.g.,* "Senators Condemn Big Price Increases for Drugs," The New York Times, http://www.nytimes.com/2015/12/10/business/senators-condemn-big-price-increases-for-drugs.html (viewed November 24, 2021).

"baked in" to future prices or price expectations to an extent that is difficult, if not impossible, to quantify. If Plaintiffs were unable to return prices to their earlier levels once Eagle's Generic were withdrawn, that uncertainty would be propagated in future net prices. Thus, Vasostrict may continue to suffer the effects of any Eagle at-risk launch indefinitely, even if Eagle's Generic were later withdrawn. In such cases, a damages award for past harm would not make Plaintiffs whole.

114. In sum, while *some* of Plaintiffs' direct harm from lost unit shipments of Vasostrict and price erosion might be calculable at the point of a future trial, much of this harm may not be calculable to the level of reasonable certainty required for inclusion in a damages award. But even to the extent this immediate harm could be estimated adequately, it would still likely undercount the full extent of Plaintiffs' indirect losses for the reasons noted below.

b. Indirect Losses

115. In addition to the likely harm Plaintiffs would suffer immediately from any premature generic entry by Eagle, Plaintiffs and Endo would likely also suffer (irreparable) harm due to second-order effects of losing those profits (even if just temporarily), which are likely to be unquantifiable, but substantial. These additional sources of irreparable harm include a severe adverse financial

impact due to the loss of a critical source of funds, R&D losses, diminished access to capital, and a diminished ability to retain current and attract new skilled employees.

(i) Financial Viability / Flexibility Losses

116. As discussed above, Vasostrict is Endo's highest-selling product [redacted] representing approximately [redacted] of its net sales revenue and approximately [redacted] of its gross profit in 1H 2021.[205] Losing [redacted] for such a significant product (even if just for a limited period) would have a significant adverse financial impact on virtually any company. However, the financial impact of losing Vasostrict would be especially severe in this case due to Endo's currently challenging financial condition.

117. Endo has incurred large before-tax losses from continuing operations over the past five years, much of which reflects restructuring and asset impairment charges that were taken on its generic pharmaceutical segment,[206] as well as legal exposure associated with its prior sale of opioid and other products.[207]

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205 Tab 4.

206 Endo 2020 10-K, at pp. F-33 to F-35; Endo International, PLC SEC Form 10-K for the fiscal year ended December 31, 2017 ("Endo 2017 10-K"), at pp. 23, F-23 to F-26.

207 These products include Endo's Opana ER (extended release oxymorphone) and transvaginal surgical mesh products. *See* Endo 2020 10-K, at pp. 31-33, 39, 61, 66, 69, 71, 73, F-11, F-25, F-27, F-42 to F-44. *See also*, "Drugmaker Endo settles opioid claims by New York, counties for $50 mln," Reuters,

To support continued operations, Endo has taken on significant debt (over $8 billion as of 3Q 2021),[208] which represents approximately 90 percent of the company's total assets.[209] Endo pays over $500 million per year in interest to its debt holders, which represents about 20 percent of its total annual net revenue.[210] Endo also has restructured this debt in recent years by replacing non-secured debt with secured debt.[211] Moreover, this debt is accompanied by "covenants" that restrict Endo's operating and financial flexibility by, for example, limiting its ability to pursue new acquisitions, sell assets, repurchase its stock, take on additional debt, etc.[212]

118. Consequently, Endo's difficult financial condition would compound the harm Plaintiffs would suffer from the rapid erosion of Vasostrict's over [redacted] in profits[213] following an early entry by Eagle, directly, by reducing

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https://www.reuters.com/business/healthcare-pharmaceuticals/drugmaker-endo-settles-opioid-claims-by-new-york-counties-50-mln-2021-09-10/ (viewed November 24, 2021).

208 Endo 3Q 2021 10-Q, at p. 1.

209 Calculated as 87.1 percent = $8.1 billion / $9.3 billion. *See* Endo 3Q 2021 10-Q, at p. 1. [redacted]

See also, "Market capitalization of Endo International (ENDP)," CompaniesMarketCap.com, https://companiesmarketcap.com/endo-international/marketcap/ (viewed December 5, 2021).

210 Endo 2020 10-K, at p. F-7; Endo 2Q 2021 10-Q, at p. 18. *See* Tab 4.

211 Endo 2020 10-K, at p. F-37; Endo 2017 10-K, at p. F-43; PAR-VASO_0298928.

212 Endo 2020 10-K, at pp. 36, 70.

213 Tab 20.

the funds available for Endo to continue investing in the development and launch of patient-enhancing new products and product improvements by Plaintiffs and Endo's other subsidiaries, and indirectly, by exacerbating the company's financial distress and threatening its (and hence Plaintiffs') long-run financial viability.

119. While a company theoretically could turn to capital markets to maintain funding for its investments (*i.e.,* issuing new debt and / or equity interest) when faced with a sudden loss of retained earnings, such alternative sources of funding are largely foreclosed to Endo (and Plaintiffs) due to the substantial debt the company already carries, the associated covenants that restrict issuing additional debt, and a stock price depressed by the company's high debt leverage and, as discussed below, remaining litigation exposure.

(ii) R&D Losses

120. Pharmaceutical companies typically rely heavily on profits generated from current product sales (*i.e.,* "retained earnings") to fund investment for the research, development, and launch of new products, or research and development for product improvements.[214] Losing [redacted]

[214] Pharmaceutical companies' heavy reliance on retained earnings is generally attributed to the primarily intangible nature of pharmaceutical assets, which are relatively illiquid and have significantly diminished value with which to compensate debt holders in case of default. The risky nature of pharmaceutical R&D creates information asymmetries

[redacted] would dramatically reduce the funds available for Endo and Plaintiffs to fund these investments. [redacted] The profits generated by Endo's remaining products would be insufficient to fund a large portion of these R&D and SG&A expenses, implying that a substantial amount of Endo's investment in new product development and market launch by Plaintiffs and Endo's other subsidiaries would have to be abandoned or curtailed. Consequently, the profits Plaintiffs and its affiliates would have obtained from these new product investments would be reduced or lost.[215]

121. The inability to fund some or all these investments due to the erosion of Vasostrict sales from any Eagle at-risk launch would result in substantial harm. Endo reported in a recent SEC filing that its "financial results depend,

between borrowers and lenders regarding the likely success of the borrowers' R&D investments, which raises the cost of lending because of the difficulty in monitoring the borrowers' incentive to accept additional risk that will be disproportionately borne by the lender in case of project failure. Harrington, Scott E., "Cost of Capital for Pharmaceutical, Biotechnology, and Medical Device Firms," in *The Oxford Handbook of the Economics of the Biopharmaceutical Industry* (2012), at pp. 2-4, 35-36; Brealey, Richard A., Stewart C. Meyers, and Franklin Allen , *Principles of Corporate Finance* (2011), Tenth Edition, McGraw-Hill/Irwin, at pp. 2-3, 8, 457-463, 716-717.

215 Bradley Declaration, at ¶¶ 30-35.

to a significant extent," on its ability "to identify, develop, obtain regulatory approval for, launch and commercialize a pipeline of commercially successful branded and generic products, including first-to-file or first-to-market opportunities,"[216] and that if it fails to do so, its "revenues, gross margin and operating results may decline."[217] It further reported that its "R&D efforts are focused on the development of a balanced, diversified portfolio of innovative and clinically differentiated product candidates,"[218] which it "periodically review[s] […] in order to better direct investment toward those opportunities that [it] expect[s] will deliver the greatest returns."[219] As of 2020, Endo's "Sterile Injectables" and "Generic Pharmaceuticals" segments "were actively pursuing approximately 80 product candidates," including "approximately 50 ANDAs pending with the FDA […] and approximately 30 additional products."[220] Other significant Endo investments include a Phase II clinical study for the use of Endo's brand drug, Xiaflex®, in the treatment of plantar fibromatosis and adhesive capsulitis, additional promotional activities to drive demand for Xiaflex®, the commercial launch of Endo's brand cellulite

216 Endo 2019 10-K, at p. 19.

217 Endo 2019 10-K, at p. 19.

218 Endo 2019 10-K, at p. 3.

219 Endo 2019 10-K, at p. 3.

220 Endo 2020 10-K, at p. 6.

treatment drug, QWO®, and the development of RTU and other product candidates in its Sterile Injectables segment.[221]

122. Moreover, to the extent that Endo and Plaintiffs would be able to obtain additional capital market financing, such funds could only be obtained at a high cost of capital that is inflated by the considerable risk the company will be unable to meet its debt obligations, a risk that would be greatly exacerbated by the loss of Vasostrict revenues and profits. Thus, investments that would have been profitable with Vasostrict's sales maintained will likely become unprofitable at the higher cost of capital at which these investments would be discounted if financed by external capital rather than Vasostrict profits.

123. Endo already has been forced into "restructuring initiatives" to reduce R&D expenditures by Plaintiffs and Endo's other subsidiaries,[222] and such reductions would undoubtedly increase with the loss of Vasostrict profits as a significant source of funding. However, identifying, quantifying, and awarding such consequential damages to Plaintiffs upon obtaining a favorable court decision following Plaintiffs' appeal is both unlikely and uncommon in patent cases, despite the significance of this harm. Determining which particular investment projects were curtailed, abandoned, or were never

221 Endo 2Q 2021 10-Q, at p. 37.

222 Endo 2Q 2021 10-Q, at p. 7.

considered due to the incremental loss of Vasostrict profits as a source of funding as opposed to an updated assessment that the project had become unprofitable would be exceedingly difficult and quite subjective.[223] Even if such projects could be definitively identified, it would also be difficult, if not impossible, to estimate reliably the streams of current and future profits those several foregone projects would have generated in a world in which Eagle had not launched prematurely. Because the magnitude of this substantial harm to Plaintiffs could not be estimated with reasonable certainty to support its inclusion in an award of damages, it likely would be irreparable.

(iii) Capital Access Losses

124. In addition to the direct loss of Vasostrict sales and profits as a source of funding for its investments due to any Eagle early generic entry, the loss of Vasostrict profits would reduce Endo's (and hence Plaintiffs') ability to fund its investments indirectly by increasing risk to its debt and equity holders, which would lead to more severe constraints on Endo's and Plaintiffs' access to external sources of capital, further restriction of their financial and operational flexibility, and additional increases in their overall cost of capital.

223 Endo noted in a recent SEC filing that "[identifying] and developing additional product candidates are prone to risks of failure." *See* Endo 2020 10-K, at p. 21.

125. Endo's current financial distress stems in large part from its legal exposure to potentially large payments in the coming years for product liability and other types of litigation related to its prior sale of opioid drug products and certain medical devices.[224] Its opioid liabilities alone have recently been estimated to amount to at least [redacted][225] The continuing risk of being liable for large additional payments related to this lingering litigation exposure, in combination with Endo's high debt leverage and associated covenants restricting its operational and financial flexibility, has placed the company in a precarious financial position that threatens its (and hence Plaintiffs') long-run viability. The deterioration in Endo's financial position due to this risk is reflected in the financial market's perception of Endo's debt as being very risky, with ratings of Caa1 by Moody's[226] and CCC+ by Standard & Poor's, reflecting "the potential for an event of default within the next 12 months […]."[227]

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224 Endo 2020 10-K, at pp. 17, 24-25, 32.

[redacted]

226 Moody's Investor Service, "Rating Action: Moody's Downgrades Endo's CFR to Caa1; Outlook Negative," (August 25, 2021) ("Moody's, August 25, 2021"), at p. 1.

227 S&P Global Ratings, "Endo International PLC Downgraded to 'CCC+' from 'B-' on Vasostrict Trial Outcome; Outlook Negative," (September 2, 2021) ("S&P, September 2, 2021"), at p. 1.

126. The loss (even if just temporarily) of its highest-selling product and primary source of profits to fund its (and hence Plaintiffs') investments and litigation-related payments would significantly increase the high risk already faced by Endo's current and prospective future investors in its debt and equity. This increased risk would considerably worsen Endo's already difficult financial situation and even threaten its (and Plaintiffs') overall solvency and long-run viability. Specifically, losing Vasostrict sales to early generic entry would likely cause current holders of Endo's debt to impose even more severe covenants to restrict the financial and operational actions Endo could pursue to improve its business or financial situation.[228] Prospective future creditors would be less willing to extend loans to Endo (or Plaintiffs) or otherwise would only be willing to do so at higher rates of interest than they are currently willing to accept. Likewise, the reduction in Plaintiffs' and Endo's expected future cash flows from the loss of Vasostrict sales, combined with the greater risk to Endo's long-run viability resulting from the loss of those sales, would reduce the price investors would be willing to pay to purchase Endo's stock. Consequently, Endo and Plaintiffs would be even more constrained in their ability to secure external financing for their product investments, and what funds they could secure would be at a higher cost of capital, both of which

228 Endo 2020 10-K, at pp. 31, 33-36.

would further reduce Endo's and Plaintiffs' investment in profitable projects beyond the direct impact of losing Vasostrict's profits as a funding source.

127. Reflecting the dire consequences of possible generic vasopressin entry in conjunction with continuing litigation risks on its financial situation, Endo reported in a recent SEC filing:

> The introduction of any competing versions of VASOSTRICT® could result in significant reductions to our market share, revenues, and cash flows, both in the short term and long term, and could have a material adverse effect on our business, financial condition, results of operations and cash flows.[229]
>
> Our operations are subject to many significant risks and uncertainties, including those related to generic competition and legal challenges that could impact our key products, including VASOSTRICT®, outstanding and future legal proceedings and governmental investigations, including those related to our sale, marketing and/or distribution of prescription opioid medications, and others. Any negative development or outcome in connection with any or [all] these risks and uncertainties could result in significant consequences, including one or more of the following: […]
>
> - causing us to be unable to maintain compliance with or making it more difficult for us to satisfy our financial obligations under certain of our outstanding debt obligations, causing a downgrade of our debt and long-term corporate ratings (which could increase our cost of capital) and exposing us to potential events of default (if not cured or waived) under financial and operating covenants

229 Endo 3Q 2021 10-Q, at p. 31.

> contained in our or our subsidiaries' outstanding indebtedness;
> - limiting our ability to incur additional borrowings under the covenants in our then-existing facilities or to obtain additional debt or equity financing for working capital, capital expenditures, business development, debt service requirements, acquisitions or general corporate or other purposes, or to refinance our indebtedness; and/or
> - and/or causing a significant reduction in our short-term and long-term revenues and/or otherwise causing us to be unable to fund our operations and liquidity needs, such as future capital expenditures and payment of our indebtedness.[230]

128. Endo's challenging financial position, and the significant degree to which the Vasostrict revenues loss due to Eagle's early generic entry would threaten its (and hence Plaintiffs') financial viability, is reflected in recent downgrades of Endo's debt by both major ratings agencies. Standard & Poor's recently downgraded Endo's stock from B- to CCC+ ("outlook negative"), noting that its "downgrade […] reflects our expectation for weakening credit metrics in 2022 and 2023 from Eagle's launch of a generic Vasostrict, raising adjusted gross debt to EBITDA to above 9x from the high 7x area and leading us to believe the capital structure is likely unsustainable."[231] The ratings agency

230 Endo 3Q 2021 10-Q, at pp. 54-55.

231 S&P, September 2, 2021, p. 1.

further expects "the lower operating cash flow and potential opioid-related liabilities to constrain the company's ability to invest in the pipeline."[232]

129. Moody's also recently downgraded Endo's debt rating from B3 to Caa1 ("negative outlook"),[233] citing among other factors the company's "product concentration risk as Vasostrict, Endo's largest product, contributes more than 20% of Endo's earnings. Uncertainty around patent litigation on Vasostrict exposes it to risk of earnings declines that would increase financial leverage if generic challengers are successful."[234] Moody's warns that in addition to negative events related to its opioid-related litigation, "[a] negative outcome stemming from ongoing patent litigation on its largest product, Vasostrict, could also lead to a [further] downgrade," and that "Endo's capacity to absorb a settlement would depend on potential cash outflows relative to its annual free cash flow as well as developments in the rest of its business, such as ongoing patent litigation on Vasostrict."[235]

130. The harm that Plaintiffs and Endo would suffer from these indirect financial impacts of losing Vasostrict sales to any at-risk entry by Eagle's Generic

232 S&P, September 2, 2021, p. 1.

233 Moody's, August 25, 2021, p. 1.

234 Moody's, August 25, 2021, p. 2.

235 Moody's, August 25, 2021, p. 3.

would be even more difficult to quantify than the direct financial harm from losing those sales that I discussed above. In addition to identifying which investment projects would be foregone by Plaintiffs, which would have been successful, and the magnitude of sales these projects would have generated, a damages estimate would also have to ascertain the incremental impact of lost Vasostrict sales in constraining Plaintiffs' and Endo's access to and cost of securing external debt and equity capital that could otherwise have funded these investments. A variety of other factors, such as additional payment for litigation damages and settlements, the commercial performance of other Endo products, the success or failure of R&D projects, increasing interest rates, etc., significantly complicate this exercise, such that it is unlikely the incremental impact could be estimated to the degree of reasonable certainty required for compensation in a damages award. Thus, although this indirect financial harm that would result from any premature generic launch by Eagle would likely be substantial, such that it even threatens the viability of Endo Plaintiffs as going concerns, it would likely go uncompensated, and thus, would likely be irreparable.

(iv) Employment Losses

131. The loss of Vasostrict sales and the associated financial harms that would result from any premature generic entry by Eagle would likely lead to the loss

of some portion of Endo's (including Plaintiffs') R&D staff and salesforce, whose employment could no longer be funded or who would seek more lucrative or rewarding opportunities elsewhere. Such staff attrition would reduce Plaintiffs' and Endo's innovative output and marketing effectiveness, putting them at a competitive disadvantage with other brand pharmaceutical firms that compete primarily on product differentiation through innovation and marketing.

132. Moreover, Plaintiffs' R&D scientists and salesforce have developed technical and specialized knowledge that is highly tailored to Plaintiffs' products and product candidates, including the underlying chemical, biochemical, and physiological processes related to their use. It would be difficult, time-consuming, and costly to replace this specialized human capital after resolution of the patent litigation, especially considering the adverse reputational harm Plaintiffs and Endo would likely sustain in the eyes of prospective new hires because of Eagle's early entry.

133. Accordingly, Endo wrote in a recent SEC filing that "[because] of the specialized scientific nature" of its business, Endo's "ability to develop products and to compete with […] current and future competitors will remain highly dependent, in large part, upon [its] ability to attract and retain qualified scientific, technical and commercial personnel," and that if it is "unable to

retain […] key personnel and continue to attract additional professional staff, [it] may be unable to maintain or expand [its] business."[236] Endo also wrote:

> The loss of key scientific, technical and commercial personnel or the failure to recruit additional key scientific, technical and commercial personnel could have a material adverse effect on our business, financial condition, results of operations and cash flows. While we have consulting agreements with certain key individuals and institutions and have employment agreements with our key executives, we may be unsuccessful in retaining personnel or their services under existing agreements. There is intense competition for qualified personnel in the areas of our activities and we may be unable to continue to attract and retain the qualified personnel necessary for the development of our business.[237]

134. The magnitude of harm Plaintiffs would suffer from these staff reductions would ultimately be manifested as forgone sales and profits on future products that either would not be developed or that would generate lower sales and profits due to inferior product development or deficient salesforce support. Identifying the products affected by the staff reductions and estimating the incremental profits they would have generated had the R&D staff and salesforce been retained at the but-for world levels for purposes of awarding damages would be virtually impossible. Thus, Plaintiffs' harm resulting from these staff reductions would likely be irreparable.

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236 Endo 2020 10-K, at p. 28.

237 Endo 2019 10-K, at p. 37.

5. Collectability

135. Even assuming the full extent of the harm to Plaintiffs could be estimated accurately and reflected in a damages award, Plaintiffs could face substantial impediments that would preclude them from collecting the full compensation from such an award should Eagle ultimately be found to be infringing the Patents at Issue.

a. Eagle's Ability to Pay Damages

136. Eagle may not be financially capable of paying an appropriate award of damages in this case, which would likely amount to several hundred million dollars. As discussed above, Eagle is a relatively small pharmaceutical company that currently has a portfolio of three marketed injectable products, Ryanodex® (dantrolene sodium), Belrapzo® (bendamustine solution), and Bendeka® (bendamustine rapid infusion).[238] Eagle markets only the first two of these products. Teva markets Bendeka® for Eagle.[239] Eagle obtained FDA approval for a fourth product, Pemfexy® (pemetrexed) in February 2020, but does not expect to be able to launch the product until 2022.[240]

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238 Eagle Pharmaceuticals, Inc. SEC Form 10-Q for the quarterly period ended June 30, 2021 ("Eagle 2Q 2021 10-Q"), p. 9.

239 Eagle 2Q 2021 10-Q, p. 9.

240 Eagle 2Q 2021 10-Q, p. 9.

137. Eagle generated total revenues of $187.8 million in 2020, which included $72.3 million in sales revenues from its three products, and $115.5 million in royalty and license revenue.[241] In 2020, the company generated annual profit of $33.0 million and operating cash flow of $49.5 million on this revenue.[242] As of September 2021, Eagle had $171.7 million in current assets, including $99.7 million in cash and cash equivalents.[243] The company's total market value has [redacted] since June 2021, primarily reflecting the prospective value of potential products in its R&D pipeline.[244]

138. A likely damages award amounting to [redacted][245] While Eagle could generate profits from its generic sales, if it were to launch at-risk, those profits will likely be substantially lower than the profits that Plaintiffs stand to lose from any such entry by Eagle [redacted]

241 Eagle 2020 10-K, at pp. F-6, F-19.

242 Eagle 2020 10-K, at pp. F-6, F-8.

243 Eagle Pharmaceuticals, Inc. SEC Form 10-Q for the quarterly period ended September 30, 2021 ("Eagle 3Q 2021 10-Q"), at p. 1.

244 Busby, Daniel, and Steve Daddeo, "Eagle Pharmaceuticals," RBC Capital Markets (August 9, 2021), at p. 1; Eagle 2020 10-K, p. 6. Market value range is from Bloomberg Data. *See also*, "Market capitalization of Eagle Pharmaceuticals (EGRX)," CompaniesMarketCap.com, https://companiesmarketcap.com/eagle-pharmaceuticals/marketcap/ (viewed December 5, 2021).

245 Eagle 3Q 2021 10-Q, at p. 1.

[redacted] And because Eagle's market capitalization primarily represents the value of illiquid assets, Eagle would have very limited ability to sell assets to fund a damages payment. Consequently, it is highly questionable that Eagle would have the financial capability to compensate Plaintiffs for their full harm through a damages award, and to this extent, Plaintiffs harm would be irreparable.

b. Plaintiffs' Ability to Collect Damages

139. As discussed above, Plaintiffs' and Endo's financial position is, at best, challenging. Endo's debt has recently been downgraded to reflect that it has "the potential for an event of default within the next 12 months stemming from opioid-related litigation or the possibility of a distressed exchange."[246] The loss of Vasostrict sales to any early Eagle entry and / or a large damages judgment against Endo in one or more of its various opioid-related litigation cases presents the considerable risk that Endo would become insolvent and, in the worst case scenario, thrust into bankruptcy before a final decision on Eagle's infringement, including any appeals, would be forthcoming. If Endo

246 S&P, September 2, 2021, p. 1. Similarly, J.P. Morgan noted, on November 5, 2021, that there were "fairly significant challenges facing the company between its high leverage, still-pending opioid liabilities, and an uncertain outlook for Vasostrict," and that "[opioids] remain a key focal point for the Endo story going forward" and "a settlement [was seen] as far from certain." *See* Schott, Chris, *et al.*, "Endo International PLC – 3Q Takeaways: Significant Beat on Vasostrict and Gx Launches but Longer-term Uncertainties Remain," J.P. Morgan, November 5, 2021, at pp. 1, 3.

were forced to liquidate, Plaintiffs would not be able (or their creditors might find it difficult) to collect any damages that would be awarded to compensate for Eagle's infringement. And even if Endo would be able to reorganize under bankruptcy protection, any damages paid by Eagle would largely or exclusively be claimed by Endo's creditors. Thus, there is significant risk that Plaintiffs would not be able to collect full damages compensation for their harm, and therefore, that such harm would be irreparable.

C. Balance of Hardships

140. For several reasons, the harm that Plaintiffs would suffer if Eagle were permitted to launch the Eagle Generic at-risk would substantially outweigh the potential harm that Eagle might bear if an injunction were granted.

141. The profits that Plaintiffs would lose would accrue at the rate of hundreds of millions of dollars annually, reflecting their 100 percent share of the marketplace and their relatively high brand profit margin in the absence of Eagle's Generic entry (all of which were the results of many years and "significant time and resources" in investments undertaken by Plaintiffs).[247]

247 "Endo Announces Issuance of Vasostrict Patent," Endo, https://investor.endo.com/news-releases/news-release-details/endo-announces-issuance-vasostrictr-patent (viewed November 23, 2021).

142. [redacted]

143. [redacted]

144. [redacted]

[redacted]

[redacted]

145. Consequently, the profits that Eagle would forgo may be based on a sales volume of [redacted] or less of the current sales volume of Plaintiffs' brand Vasostrict and on a price that would be considerably below the current brand Vasostrict price for its first 180 days on the market. [redacted] Thus, the lost profit harm that Plaintiffs would suffer based on 100 percent of the market would vastly exceed the lost profit harm that Eagle would sustain on [redacted] market share and sharply lower generic prices.

146. Further, as discussed above, a damages award would fail to compensate Plaintiffs for a large portion of the substantial harm they would suffer if Eagle were permitted to launch the Eagle Generic at-risk in the absence of an

249 [redacted]

injunction. Those harms include losses in financial viability / flexibility, R&D investments, access to capital, and employment.

147. In contrast, if an injunction were granted, Plaintiffs would be required to post a bond from which Eagle could be compensated for the much less significant, but more quantifiable, harm it would sustain.

148. If Eagle's generic product were not enjoined, it would have an immediate and substantial adverse impact on Endo's (and hence Plaintiffs') ongoing business and precarious financial condition for the reasons discussed in the sections above, from which Endo and Plaintiffs may never be able to recover. In addition, Endo and Plaintiffs would be forced to change their commercial and R&D strategies, cut budgets, and lay off employees. These negative effects are not easily reversed and could persist for years.

149. In contrast, Eagle has never sold a generic version of Vasostrict. It is unlikely that Eagle's financial viability and strategic plans would be disturbed by having to delay its launch of its Generic until the final resolution of this litigation, especially considering that Eagle could potentially retain its 180-day exclusivity period and that it ultimately would receive the profits it would have generated during the injunction period via compensation by Endo's bond.

150. Entry of an injunction pending appeal would not disrupt Eagle's pursuit of business opportunities for generic products other than vasopressin. Eagle's product portfolio includes, for example, EP-4104 (dantrolene) and EGL-5385-C-1701 (fulvestrant).[250] Although Eagle's interest in marketing a generic version of Vasostrict indicates that the returns on generic vasopressin may be attractive, Eagle pursues many generic or other opportunities across a wide range of therapeutic areas.[251] Therefore, a generic version of Vasostrict would account for a limited portion of Eagle's portfolio, and a delayed launch would result in a loss of sales that is a small portion of Eagle's overall sales. In contrast, Vasostrict is one of Endo's and Plaintiffs' flagship "Sterile Injectables" brands and accounts for more than half of Endo's "Sterile Injectables" revenues.[252] Enjoining Eagle would have minimal impact on its businesses, and that minimal impact is compensable through a bond. Not enjoining Eagle would impose serious financial hardship on Endo and Plaintiffs.

151. For these reasons, Plaintiffs would clearly bear much more hardship in the absence of an injunction than Eagle would sustain if an injunction is granted.

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250 Eagle 2019 10-K, at pp. 8-12.

251 Eagle 2019 10-K, at pp. 8-12.

252 *See, e.g.,* Endo 2019 10-K, at p. 4.

D. Public Interest

152. The last factor that I have been asked to examine is the impact of the requested relief on the public interest. That is, I have been asked to assess whether the requested relief would run counter to the public interest or, alternatively, whether it would serve it.

153. As in most patent infringement cases, the question of public interest involves balancing the merits of a system that promotes vigorous competition versus one that provides strong protection for patented innovations.[253] Competition is the "organizing principle for most of the U.S. economy" and can stimulate innovation by encouraging the creation of new or better products and lower-cost production processes.[254] On the other hand, the patent system, by granting market exclusivity for a limited time, allows innovators to receive economic returns that compensate them for the significant investment risk of pioneering

253 *See*, *e.g.*, United States Federal Trade Commission, "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy," (2003), available at https://www.ftc.gov/sites/default/files/documents/reports/promote-innovation-proper-balance-competition-and-patent-law-and-policy/innovationrpt.pdf; Higgins, Matthew J., and Stuart J. H. Graham, "Balancing Innovation and Access: Patent Challenges Tip the Scales," *Science*, Vol. 326, No. 5951 (2009): 370-71; Knowles, Sherry M., "Fixing the Legal Framework for Pharmaceutical Research," *Science*, Vol. 327, No. 5969 (2010): 1083-84.

254 United States Federal Trade Commission, "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy," (2003), available at https://www.ftc.gov/sites/default/files/documents/reports/promote-innovation-proper-balance-competition-and-patent-law-and-policy/innovationrpt.pdf, at p. 1.

new technologies and incorporating them in products.[255] Both goals have substantial merit.

154. The public interest would, on net, however, be served through a finding in favor of Plaintiffs and the issuance of requested relief.

155. The public has substantial interest in preserving R&D incentives of pharmaceutical companies. As noted above, in 2014, Plaintiffs received FDA approval to market the branded version of vasopressin, a drug previously marketed by several manufacturers without FDA approval or proof of safety and efficacy. The public has substantial interest in preserving incentives for pharmaceutical companies to invest in demonstrating and ensuring safety and efficacy of existing drugs, as Plaintiffs have done for vasopressin.

156. In addition, the public has substantial interest in preserving the stability and reliability of Vasostrict supply, especially considering its emergency use nature during the COVID-19 pandemic. I understand that Plaintiffs have been able to supply Vasostrict safely and reliably in quantities that are more than

255 *See*, *e.g.*, Grabowski, Henry G., and John M. Vernon, "Effective Patent Life in Pharmaceuticals," *Int. J. Technology Management,* Vol. 19, Nos. 1/2 (2000): 98-120; Lehman, Bruce, "The Pharmaceutical Industry and the Patent System," *International Intellectual Property Institute* (2003): 1-14; Grabowski, Henry G., "Patents and New Product Development in the Pharmaceuticals and Biotechnology Industries," in *Science and Cents: The Economics of Biotechnology* (2002), pp. 87-104, edited by John Duca and Mine K. Yucel (Federal Reserve Bank of Dallas).

sufficient to satisfy marketplace demand.[256] I also understand that Plaintiffs never experienced a shortage of supply for its Vasostrict customers, and that they anticipate being able to continue supplying the entire vasopressin marketplace for the foreseeable future.[257]

157. On the flipside, it is unclear whether Eagle, if allowed to launch its Generic at-risk, will be able to reliably supply vasopressin products to its customers.[258] Eagle does not own any manufacturing facilities and relies on third-party manufacturers,[259] which can introduce further unreliability in its supply chain. As noted by Eagle in its financial disclosure,

> We do not own any manufacturing facilities. The manufacture of sterile injectables is highly reliant on very complex sterile techniques and personnel aseptic techniques which present significant challenges and requires specialized expertise. Further, sterile processes have a high level of scrutiny by regulatory agencies. Consequently, we utilize a network of third party manufacturers for production of our products. All manufacturers are monitored and evaluated by our quality department to assess compliance with regulatory

256 Bradley Declaration, at ¶¶ 9-11.

257 Bradley Declaration, at ¶¶ 9-11.

258 Considering the emergency use nature of Vasostrict in treating COVID-19 patients, even temporary disruptions to stable Vasostrict / vasopressin supply may harm the public interest, even if Plaintiffs can replace Eagle in supplying Vasostrict / vasopressin after shortages caused by Eagle's unreliable supply.

259 Eagle 2020 10-K, at p. 15.

> requirements and our internal quality standards and benchmarks.[260]

158. Further, as noted above, Vasostrict is primarily used in hospitals.[261] In this matter, the purported benefits of price reductions due to generic entry may primarily be retained by insurers and large institutional providers, rather than by the ultimate patients. In addition, low generic prices can result in drug shortages, which, considering the emergency use nature of Vasostrict during the COVID-19 pandemic, can lead to significant consequences, including loss of life. The FDA has written

> [Drugs that have experienced shortages] were more likely to be relatively low-price and financially unattractive drugs and were more likely to be sterile injectables. Shortages often occurred as a result of disruption in supply due to a variety of factors. Importantly, prices rarely rose after shortages began, and during shortages, production typically did not increase enough to restore supply to pre-shortage levels. Many manufacturers reported discontinuing the production of drugs before a shortage for commercial reasons […]. These results suggest a broken marketplace, where scarcity of drugs in shortage or at risk for shortage does not result in the price increases predicted by basic economic principles.[262]

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260 Eagle 2020 10-K, at p. 15.

261 Bradley Declaration, at ¶¶ 5-6, 10-11, 32.

262 "Statement on FDA's new report regarding root causes and potential solutions to drug shortages," FDA, https://www.fda.gov/news-events/press-announcements/statement-fdas-new-report-regarding-root-causes-and-potential-solutions-drug-shortages (viewed November 23, 2021).

IV. CONCLUSIONS

159. Based upon review and analysis of the evidence that I have received to date, it is my opinion that Plaintiffs are likely to be irreparably harmed if there were to be an at-risk launch of the Eagle Generic. The FDA approved the Eagle Generic yesterday and, I understand, Eagle has represented that it intends to launch at-risk.[263] If Eagle actually launches at-risk, it would be exceedingly difficult to calculate all of the harm to Plaintiffs resulting from that launch with reasonable certainty and grant an adequate damages award after a later damages trial covering the full extent of the impact that Plaintiffs would suffer as a result of the generic launch.

160. Furthermore, it is my opinion that the balance of hardships in this matter weighs in favor of Plaintiffs. The likely harm here will severely threaten Plaintiffs' business and, perhaps, their corporate viability. On the other hand, postponing the launch of this potential business line until after the appeal is resolved would have limited financial and strategic impact on Eagle, particularly considering that it has not yet been in the business, as Plaintiffs have for many years.

263 https://investor.eagleus.com/press-releases/news-details/2021/Eagle-Pharmaceuticals-Announces-FDA-Maintains-Prioritization-of-ANDA-for-Vasopressin/default.aspx (viewed December 4, 2021).

161. Finally, it is my opinion that the public interest would, on balance, be served through a finding in favor of Plaintiffs and the issuance of the requested preliminary injunction. Not only would such a finding confirm the merits of a strong patent protection system and the innovation incentives it creates, but it would not disrupt (and likely would ensure) the uninterrupted supply of vasopressin to patients who may suffer from life-threatening health emergencies.

John C. Jarosz

December 16, 2021